

## Hematology analyzers

## Hematology analyzers: an overview of what's new

Brendan Dabkowski

Putting their money where their market is, companies in CAP TODAY's hematology analyzers product guide are introducing systems to meet growing test demands and the need for enhanced functionality.

"Automated hematology systems with advanced, clinically relevant parameters that can potentially impact treatment guidelines, care pathways, patient flow, and return on investment are essential," says Alan Burton, director of marketing, hematology, at Sysmex America. To this end, Sysmex added to its product lineup the XT-4000i automated hematology analyzer. The XT-4000i provides 34 parameters, including immature granulocyte and reticulocyte hemoglobin. It has a body fluid-specific mode that provides a reportable RBC count, WBC count, WBC differential, and total count for all common body fluid samples. The system, Burton says, can run 100 samples per hour and uses fluorescent flow cytometry, hydrodynamic focusing, and advanced cell-counting methods to deliver rapid results. The XT-4000i can be used with the company's Work Area Manager decision support software, he adds, to improve sample and data workflow and decrease turnaround time.

Sysmex recently launched its cell image analysis portfolio (not featured in the product guide), which includes the CellaVision DM1200 and DM96 systems for mid-size to large hematology laboratories and the Medica EasyCell Assistant for smaller hematology labs.

Abbott Hematology has added to its hematology program two software packages—V3 and V4—for the company's Cell-Dyn Sapphire hematology analyzer, says Bill Bailey, U.S. marketing manager, hematology. Both software bundles allow Sapphire users to troubleshoot problems and receive updates remotely through Abbott-Link, which, he says, translates to improved reliability and increased uptime for high-volume hematology labs.

Abbott launched in June the Pathfinder sample management system. The product, says Bailey, combines "process management, Cell-Dyn instrument technology, comprehensive middleware, and logical sample management to reduce manual steps and optimize technologist efficiency and productivity."

Finally, Siemens Healthcare Diagnostics recently introduced additional automated body fluid-specific applications to its Advia 2120i system to complement the company's cerebrospinal fluid assay. Automating these labor-intensive assays allows laboratories to better balance rising work volumes with decreasing staffing, says Fred Stelling, director of global hematology marketing. Looking to the future, Siemens is focusing on integrating hematology results and other lab data into a "wider network of intelligent information management," he says.

CAP TODAY's guide to hematology analyzers includes products from the aforementioned manufacturers and from Beckman Coulter and Horiba Medical. Companies supplied the information listed. Readers interested in a particular system should confirm it has the stated features and capabilities.

Brendan Dabkowski is CAP TODAY associate editor.

<b>Part 1 of 14</b>	<b>Abbott Hematology</b> Rick Gooch rick.gooch@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com
<b>Name of instrument</b> <b>First year installed in U.S./outside U.S./No. of units sold in 2009</b> <b>No. units installed in U.S./outside U.S./List price</b>	<b>CELL-DYN Sapphire*</b> 2005/2005/— >175/>750/\$250,000
<b>Test menu:</b> • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, % neut, mono, lymph, eos, baso): • Laboratory • Flags	standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8 — band, IG, blast, variant lymph, nvWBC, rstRBC, IR, PLT clmp, ASYM, FP, CD61 agglutination, clot detected during aspiration, short sample — — — CD61 for PLTs, CD3/4, CD3/8 (immuno T-cell)
<b>FDA-cleared tests but not clinically released</b> <b>Tests not available but submitted for clearance</b> <b>Tests in development</b> <b>For research use only</b> <b>Tests unique to analyzer</b>	— — — — CD61 for PLTs, CD3/4, CD3/8 (immuno T-cell)
<b>Differential method(s) used</b> <b>Linearity:</b> • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%) <b>Precision:</b> • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct <b>Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation</b>	MAPSS (Multi-Angle Polarized Scatter Separation) and three-color fluorescence 0.4–250.0 × 10 <sup>3</sup> µL/0.22–7.50 × 10 <sup>6</sup> µL 1.0–24.8 g/dL/11.0–2,000.0 × 10 <sup>3</sup> µL 37.0–179 fL (MCV) ≤2.7 percent/≤1.5 percent ≤1.0 percent/≤4.0 percent ≤1.0 percent (MCV) neut% r=0.942 slope=0.947 y=0.446; lym% r=0.936 slope=0.943 y=2.811; mono% r=0.623 slope=1.057 y=0.851; eos% r=0.446 slope=1.024 y=0.288; baso% r=0.232 slope=0.257 y=0.350 PLT clumps, neutrophil aggregates, HbC crystals, lyse-resistant RBCs, cryoglobulin, cryofibrinogen, fragmented WBC, NRBC
<b>Interfering substances:</b> • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	autoagglutination, cold agglutinins, elevated WBC, giant PLTs, hemolysis, sm WBC autoagglutination, cold agglutinins, elevated WBC, giant PLT, hemolysis, hyperglycemia auto and cold agglutination, cryoglobulin, cryofibrinogen, giant PLT, micro RBC, PLT clumps, RBC fragments, WBC fragments, PLT satellitism  lipids>700 mg/dL, WBCs>250 × 10 <sup>9</sup> /L, bilirubin>33 mg/dL, HbC crystals
<b>Interfering substances: differential</b>	see WBC
<b>Age- and sex-specific reference ranges</b> <b>Maximum CBCs per hour/Maximum CBCs and differentials per hour</b> <b>Recommended average frequency of calibration</b>	yes 105/105 six months verification
• Modes calibrated/parameters calibrated <b>Frequency of blood/latex controls</b> <b>Minimum specimen volume open/closed/Sample dead volume closed</b> <b>Tube sampling supported</b> <b>Veterinary capability</b> <b>Microsample capability</b> <b>Prepares microscopic slides automatically or flags problems for slide prep</b> <b>If automatic slidemaker available, No. installed/list price</b>	open-closed single procedure/WBC, RBC Hb, MCV, PLT, MPV per regulatory requirement/— 120 µL/120 µL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes yes (11.5–13 × 65–75 mm, 10.25 × 64 mm, 8.5 × 66 mm [Sarstedt Monovette]) no yes no —/\$125,000
<b>Archives patient data for later comparison</b> <b>Patient-specific archiving</b> <b>Maximum archived data accessible when system online</b> <b>Memory capacity—numeric results—No. specimens</b> <b>Memory capacity—histo/cytograms—No. specimens</b> • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report <b>Saved results can be recalled and retransmitted</b> <b>Saved data can be sorted for reprocessing or report transmission</b> <b>Performs delta checks</b> <b>Tags and holds results for followup, confirmatory testing, or rerun</b> <b>Parameters for flags for holding samples are defined by</b> <b>Some results can be transmitted to LIS while others held</b> <b>Scattergram display: cell-specific color</b> <b>Histogram display: color with threshold</b> <b>Choice of desired specimen and/or result information displayed</b>	yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes
<b>LIS interface formats supported</b> <b>Information transferred on LIS interface</b>	ASTM 1394 numeric and flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders
<b>LOINC codes transmitted with results</b> <b>How labs get LOINC codes for reagent kits</b> <b>Optional data management or collation system</b> • Software features	no — yes enhanced QC, data archiving, data collation from multiple instruments, remote viewing
<b>Interface available or planned to automate specimen-handling system</b> <b>Bar-code symbologies read on tube</b>	none Codabar, codes 39 and 128, interleaved 2 of 5
<b>Accommodates bar-code placement per CLSI standard Auto2A</b>	yes
<b>Time required for maintenance by lab personnel</b> <b>Onboard maintenance records</b> <b>Time from communication of problem to engineer on site</b> <b>Onboard diagnostics/limited to software problems</b> <b>Manufacturer can perform diagnostics via modem</b>	daily: 30 seconds; weekly: 10 minutes; monthly: 5 minutes yes — yes/no yes
<b>Acquisition program based on cost-per-reportable result</b>	no
<b>Distinguishing features (supplied by company)</b>	four optical and three fluorescent detectors provide multiple scatterplot analysis; 2-D optical platelets avoid interferences; fluorescent analysis of reticulocytes, NRBCs, and three-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections  *please see the CELL-DYN Sapphire operator's manual for product labeling, including warnings, limitations, and precautions

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

# Hematology analyzers

Part 2 of 14	Abbott Hematology Rick Gooch rick.gooch@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com	Abbott Hematology Karen Busch karen.busch@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	CELL-DYN Ruby* 2006/2006/— >350/>850/\$185,000	CELL-DYN Emerald* 2009/2008/0 >500/>200/\$30,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, percent# neut, mono, lymph, eos, baso): • Laboratory • Flags	standard menu (left) plus: MPV, RDW, retic #& percent — NRBC, FWBC, NWBC, RRBC, band, IG, blast, variant lymph, RBC morph., DFLT, MCHC, LRI, URI, LURI, ATYPDEP, high/low interp. message, WBC — — atypical depolarization flag	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, lymph percent#, gran percent#, mid percent#, RDW, MPV — dispersional data alerts, suspect measurand flags and count invalidation flags — — none
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	— — — — atypical depolarization flag	— — — — none
Differential method(s) used Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (percent) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	MAPSS (Multi-Angle Polarized Scatter Separation) 0.02–246 × 10 <sup>3</sup> /μL/0.00–7.50 × 10 <sup>6</sup> /μL 0.00–25.0 g/dL/0.00–3,000 × 10 <sup>3</sup> /μL 58–139 fL: (MCV) 2.4 percent/1.8 percent 1.4 percent/3.8 percent 0.8 percent (MCV)	impedance counting 0.4–96.1 K/μL/0.22–7.61 M/μL 3.3–24.6 g/dL/9–1,375 K/uL 5.3–75.6 percent (Hct)/48.8–115 fL (MCV) 3.5 percent (95 percent confidence limit)/2.0 percent (95 percent confidence limit) 2.1 percent (95 percent confidence limit)/6.1 percent (95 percent confidence limit) 1.7 percent Hct (95 percent confidence limit)/0.8 percent MCV (95 percent confidence limit) —
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	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	—
Interfering substances: • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, PLT clumps, cryofibrinogen, cryoglobulin  elevated WBC, increased numbers of giant PLT, autoagglutination, in vitro hemolysis MCV: elevated WBC, hyperglycemia, in vitro hemolysis, increased number of giant PLTs  WBC fragments, in vitro hemolysis, microcytic RBC, cryofibrinogen, cryoglobulins, PLT clumping, increased number of giant PLT  elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lytic-resistant RBC	cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), autoagglutination, clotting, hemolysis (in vitro), microcytic red cells 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 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 carboxyhemoglobin (>10 percent), cryoglobulin, cryofibrinogen, hemolysis (in vivo) heparin, high white cell count (>50,000 K/μL), hyperbilirubinemia, lipemia, monoclonal proteins platelet aggregates, NRBCs, giant platelets, cryoglobulins, incomplete lysis of RBC, small lymphocytes, fibrin clots, shift in WBC cell distribution due to EDTA anticoagulant equilibration
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration	yes 84/84 six months verification	yes 60/60 scheduled calibration of the CELL-DYN Emerald must conform to the guidelines established by the regulatory agencies governing the laboratory open mode, as system has only one mode/WBC, RBC, HGB, MCV, PLT per regulatory requirement/—
• Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price	open or closed/WBC, RBC, Hgb, MCV, PLT, MPV per local regulatory requirements/— 150 μL/230 μL/1.2 mL yes (13 × 75 mm) no no no —/\$125,000	9.8 μL/—/— yes (open mode) no no no —
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes no yes user or vendor yes yes yes yes	yes no 60,000 on USB and 1,500 results on internal memory 60,000 on USB and 1,500 results on internal memory 60,000 on USB and 1,500 results on internal memory yes yes yes yes no no no no no yes
LIS interface formats supported Information transferred on LIS interface	LIS1/LIS2 CLSI 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	proprietary (instrument or vendor specific) numeric and flag results, instrument to LIS
LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube	no — yes enhanced QC, data archiving, data collation from multiple instruments — Codabar, codes 39 and 128, interleaved 2 of 5, ISBT	no — no — 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 yes
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes
Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	daily: 30 seconds; weekly: 5 minutes; monthly: 10 minutes yes — yes/no yes	daily: 3 minutes; monthly: 5 minutes; bi-annually: 10 minutes yes dependent upon service contract no/no no
Acquisition program based on cost-per-reportable result	no	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

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

## Hematology analyzers

Part 3 of 14	Abbott Hematology	Beckman Coulter
	Rick Gooch rick.gooch@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com	Jim Cureton jdcureton@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4942 www.beckmancoulter.com
Name of instrument	CELL-DYN 3700*	UniCel DxH 800
First year installed in U.S./outside U.S./No. of units sold in 2009	1999/1999/—	2008/2008/2
No. units installed in U.S./outside U.S./List price	>200/>1,500/\$180,000 SL Model, \$140,000 CS Model	30/20/\$219,000 or \$229,000 with floor stand
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	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.
• Laboratory	—	—
• Flags	suspect populations, band, blast, variant lymph, IG, NRBC, RRBC, NWBC, LRI, URI, LURI, RBC morphology, FWBC, high/low interpretation message, WBC	definitive, suspect and system messages, user-definable extended decision rules, ISLH consensus rules, user-definable differential sensitivity
FDA-cleared tests but not clinically released	—	—
Tests not available but submitted for clearance	—	—
Tests in development	—	—
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 research parameters
Tests unique to analyzer	IRF, veterinary capabilities**	
Differential method(s) used	MAPSS (Multi-Angle Polarized Scatter Separation)	flow cytometric digital analysis using volume, conductivity, and five angles of light scatter, digital signal processing, advanced algorithm applications, high-definition cellular resolution, DataFusion
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L)	0–250 K/μL/0–8 M/μL	0–400/0–8.5
• Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L)	0–24 g/dL/0–2,000 K/μL	0–25.5/0–3,000
• MCV (fL) or Hct (%)	50–200 fL (MCV)	50–150
Precision: • WBC count/RBC count	≤2.5 percent/≤1.5 percent	≤3.0 percent/≤1.5 percent
• Hemoglobin/platelet	≤1.2 percent/≤5.0 percent	≤1.5 percent/ ≤3.5 percent
• MCV or Hct	≤1.0 percent (MCV)	≤1.0 percent
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	neut #&#: ≥0.95, —; lymph #&#: ≥0.94, —; mono #&#: ≥0.86, —; eos #&#: ≥0.84, —; baso #&#: ≥0.73, —	NE = ±2.0; LY, MO = ±3.0; E0, BA = ±1.0 (or 10% percent, whichever is greater), —
Interfering substances: • WBC	NRBCs (WIC only), lytic-resistant RBCs, PLT clumps, cryoglobulin and cryofibrinogen, fragile WBCs	precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant red cells, giant platelets, platelet clumps, unlysed particles >35 fL in size
• RBC	increased number giant PLTs, autoagglutination, in vitro hemolysis	very high WBC count, high concentration of very large platelets, autoagglutination
• MCV or Hct	MCV: elevated WBC count, increased number giant PLTs, hyperglycemia, in vitro hemolysis	very high WBC count, high concentration of very large platelets, autoagglutination
• Platelet	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, PLT clumps, increased number giant PLTs	platelet clumps, white cell fragments, very small red cells, red cell fragments
• Hemoglobin	increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs	severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing
Interfering substances: differential	see WBC	elevated triglycerides, precipitated elevated proteins
Age- and sex-specific reference ranges	yes	yes
Maximum CBCs per hour/Maximum CBCs and differentials per hour	90/90	>100 per hour/>100 per hour
Recommended average frequency of calibration	six months verification	two times per year or per regulatory requirements
• Modes calibrated/parameters calibrated	open and closed/WBC, RBC, Hb, MCV, PLT	CBC/RBC, WBC, Hgb, MCV, PLT, MPV
Frequency of blood/latex controls	as per regulatory requirement/—	per regulatory requirements/daily
Minimum specimen volume open/closed/Sample dead volume closed	130 μL/355 μL/1.0 mL	165 μL/165 μL/300–400 μL
Tube sampling supported	yes (13 × 75 mm)	yes (variety of sizes)
Veterinary capability	yes	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes (flags only)	yes
If automatic slidemaker available, No. installed/list price	—/\$125,000	—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Maximum archived data accessible when system online	10,000 results	40,000 stand-alone; 120,000 in workcell
Memory capacity—numeric results—No. specimens	10,000 results	40,000 stand-alone; 120,000 in workcell
Memory capacity—histo/cytograms—No. specimens	10,000 results	40,000
• Stored in conjunction with CBC data	yes	yes
• Histo/cytogram images and CBC data printed as one report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	yes
Tags and holds results for followup, confirmatory testing, or rerun	yes	yes
Parameters for flags for holding samples are defined by	user or vendor	yes
Some results can be transmitted to LIS while others held	yes	some results
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshold	yes	yes
Choice of desired specimen and/or result information displayed	yes	yes
LIS interface formats supported	proprietary	ASTM 1394 and 1381
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, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders (available with release of workcell)
LOINC codes transmitted with results	no	yes
How labs get LOINC codes for reagent kits	—	phone or Web support
Optional data management or collation system	yes	yes, BCI
• Software features	enhanced QC, data archiving, data collation from multiple instruments	enhanced QC, data archiving, data collation from multiple instruments, user-definable decision rules, ISLH rules, delta check included with DxH; Remisol Advance also available
Interface available or planned to automate specimen-handling system	—	Beckman Coulter
Bar-code symbologies read on tube	Codabar, codes 39 and 128, interleaved 2 of 5	Codabar, codes 39 and 128, interleaved 2 of 5, NW7
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 30 seconds; bi-weekly: 5 minutes; monthly: 10 minutes	daily: 2 minutes; weekly: as needed; monthly: as needed
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	—	varies
Onboard diagnostics/limited to software problems	yes/no	yes/no
Manufacturer can perform diagnostics via modem	—	yes
Acquisition program based on cost-per-reportable result	no	yes
Distinguishing features (supplied by company)	MAPSS cell-by-cell analysis; reticulocyte with reportable IRF (immature reticulocyte fraction); up to 60 different animal types may be configured for analysis  *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	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 options include DxH workcells with trackless connectivity; intelligent workload distribution; configurable with up to four analyzers; integrated slidemaker/slidestainer; consolidated database

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

## Hematology analyzers

Part 4 of 14	Beckman Coulter Jim Cureton jdcureton@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4942 www.beckmancoulter.com	Beckman Coulter Jim Cureton jdcureton@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4942 www.beckmancoulter.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	LH 1500 Hematology Automation Series 2002/2003/15 >65/25/varies	LH 780/LH 785 2006/2007/160 >460/>475/LH 780: \$214,500; LH 785: \$389,500
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %neut, %lymph, %eos, %baso):  • Laboratory • Flags  FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only	standard menu (left) plus: RDW, MPV, retic %&#, IRF, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids  — 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  — — — MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD) LH 780: MAF, RSF, RDWR-SD, RDWR-CV	standard menu (left) plus: RDW, RDW-SD, MPV, retic %&#, IRF, MPV, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids  — 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  — — — RSF, MAF, MSCV, HLR %&#, RDWR-CV, RDWR-SD, PDW, PCT, WBC research population data (RPD)
Tests unique to analyzer	IVD: NRBC, body fluids; RUO: MSCV, WBC RPD	IVD: NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD
Differential method(s) used	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate, and AccuFlex technologies	Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate, and AccuFlex technologies
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	0–400/0–8.0 0–25/0–3,000 50–200 (MCV)	0–400/0–8.0 0–25/0–3,000 50–200 (MCV)
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<1.7 percent/<0.8 percent <0.8 percent/<3.3 percent <0.8 percent (MCV)	<1.7 percent/<0.8 percent <0.8 percent/<3.3 percent <0.8 percent (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation Interfering substances: • WBC	lymph% = ±3.0%, —; neut% = ±3.0%, —; mono% = ±2.0%, —; eos% = ±1.0%, —; baso% = ±1.0%, — unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, giant PLT, PLT clumps	lymph% = ±3.0%, —; neut% = ±3.0%, —; mono% = ±2.0%, —; eos% = ±1.0%, —; baso% = ±1.0%, — unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, giant PLT, PLT clumps
• RBC • MCV or Hct • Platelet • Hemoglobin Interfering substances: differential	very high WBC, high concentration large PLT, autoagglutinins very high WBC, high concentration large PLT, autoagglutinins very small RBCs and WBC fragments may interfere very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing	very high WBC, high concentration large PLT, autoagglutinins very high WBC, high concentration large PLT, autoagglutinins (MCV) very small RBCs and WBC fragments very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes 105 per analyzer on automation system/105 per analyzer on automation system as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hb, MCV, PLT, MPV per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL, 550 µL with slidemaker/1.0 mL yes no yes yes	yes 105/105 as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hgb, MCV, PLT, MPV per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL (550 µL with slidemaker)/1.0 mL yes no yes yes
If automatic slidemaker available, No. installed/list price	>850 (U.S.)/\$110,000	>50/\$110,000
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 20,000 samples per instrument 20,000 samples per instrument 20,000 samples per instrument yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes 20,000 samples 20,000 samples 20,000 samples yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface	RS-232 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast	proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast
LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	no contact technical support yes, DL2000, Command Central enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results and graphics	no contact technical support yes, DL2000, Command Central enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results and graphics, centralized result management
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	Beckman Coulter Codabar, codes 39 and 128, interleaved 2 of 5, NW7 yes	Beckman Coulter Codabar, codes 39 and 128, interleaved 2 of 5 yes
Time required for maintenance by lab personnel	daily: automation system = 5 minutes; weekly: automation = 10 minutes; monthly: automation = 15 minutes, analyzer = 2 minutes	monthly: 2 minutes
Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	yes — yes/no yes	yes — yes/no yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	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 5 of 14	Beckman Coulter Jim Cureton jdcureton@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4942 www.beckmancoulter.com	Beckman Coulter Jim Cureton jdcureton@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4942 www.beckmancoulter.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Coulter LH 750 2001/2001/250 (U.S.) >2,400/>2,300/\$195,000	Coulter LH 500 2003/2003/200 (U.S. only) >1,300/>1,700/\$145,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso): • Laboratory • Flags	standard menu (left) plus: RDW, MPV, retic #&%, IRF, MPV, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids — user-definable age-, gender-, 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 — — — MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD)	standard menu (left) plus: retic #, retic %, MRV, IRF, RDW, MPV — user-definable age-, gender- and/or location-based reference intervals, action and critical limits; user-definable RBC morphology; gradient messages — — — PCT, PDW
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only	— — — — MSCV, HLR %&#, PDW, PCT, WBC research population data (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
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	0-400/0-8.0 0-25/0-3,000 50-200 (MCV)	0-200/0-8.0 0-25/0-2,000 50-150 (MCV)
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<1.7 percent/<0.8 percent <0.8 percent/<3.3 percent <0.8 percent (MCV)	2.5 percent/≤2.0% percent 1.5 percent/≤5.0 percent 2 percent (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	lymph% = ±3.0%, —; neut% = ±3.0%, —; mono% = ±2.0%, —; 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, —
Interfering substances: • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, giant PLT, PLT clumps very high WBC, high concentration large PLT, autoagglutinins  MCV and Hct: very high WBC, high concentration large PLT, autoagglutinins  very small RBCs and WBC fragments may interfere  very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	lyse-resistant, nucleated RBCs, frag. WBCs, agglutination WBCs, unlysed particles >35 fL, very large or agg. PLTs, fibrin, cell frag., or other debris very high WBC count, many very large PLTs, agglutinin RBCs, RBCs <36 fL, fibrin, cell fragments, or other debris MCV: very high WBC count, high concentration of very large PLTs, agglutinin RBCs, RBC fragments <36 fL, rigid RBCs 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 high WBC count, severe lipemia, heparin, lyse-resistant RBCs, turbidity such as elevated triglycerides
Interfering substances: differential	high triglycerides may affect lysing	factors that affect WBC count above or high triglycerides that affect lysing, hypogran. granulocytes, agranul. granulocytes, lyse-resist. red cells, very small or multi-population lymphocytes, elevat. trigly., precipitated elev. proteins
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration	yes 105/105 as dictated by your lab procedures, local or national regulations	yes 75/75 as dictated by your lab procedures, local or national regulations
• Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	primary/RBC, WBC, Hb, MCV, PLT, MPV per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL, 550 µL with slidemaker/1.0 mL yes (multiple sizes and styles) no yes yes, both	primary/RBC, WBC, Hb, MCV, PLT, MPV not specified/once per day 125 µL/185 µL/tube dependent yes (10.25 × 75 mm or less; 13 × 75 mm or less) no yes no
If automatic slidemaker available, No. installed/list price	>900 (U.S.)/\$110,000	—
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 20,000 samples 20,000 samples 20,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes 20,000 samples 20,000 samples 20,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	RS-232, proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, DL2000, Command Central enhanced QC, data archiving, common database, extensive decision rules, delta checking, patient results and graphics, centralized management of all instruments	RS-232, proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, DL2000, Command Central enhanced QC, data archiving, data collation from multiple instruments, common database, extensive decision rules, delta checking, patient results and graphics, centralized management of instruments
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	Beckman Coulter Codabar, codes 39 and 128, interleaved 2 of 5, NW7 yes	— Codabar, codes 39 and 128, ASTM, interleaved 2 of 5, NW7 yes
Time required for maintenance by lab personnel	monthly: 2 minutes	none
Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	yes — yes/no yes	yes — yes/no yes
Acquisition program based on cost-per-reportable result	yes	yes
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

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

## Hematology analyzers

Part 6 of 14	Beckman Coulter Jim Cureton jdcureton@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4942 www.beckmancoulter.com	Beckman Coulter Kelly Colwell KMColwell@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4110 www.beckmancoulter.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Coulter HmX 1999 HmX AL >1,140/>2,200/\$135,000	Coulter Ac•T 5diff Family; Ac•T 5diff AL 2001/2000; 2003/2003; cap pierce: not applicable, autoloader: not applicable 900/3,000/\$43,500 cap-pierce model; 300/750/\$54,500 autoloader model
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso): • Laboratory  • Flags	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV —  comprehensive high/low, definitive and suspect messages	standard menu (left) plus: RDW, MPV  atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW complete operator selectable flagging
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only	— — — PCT, PDW	— — — PCT, PDW, IMM, ATL
Tests unique to analyzer	—	—
Differential method(s) used	Coulter's 3-D VCS technology	AcV technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	0–99.9/0–7.0 0–25/0–999 50–150 (MCV)	0.4–91.3/0.3–8.0*; AL: 0.4–120.0/0.3–8.0 0–22/10–1,000*; AL: 1.3–24.0/10.0–1,000 1.8–63.8 (Hct)*
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<2.5 percent/<2.0 percent <1.5 percent/<5.0 percent <2.0 percent (MCV)	<2 percent/<2 percent <1 percent/<5 percent <1.0 percent (Hct); AL: <2.0% (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	lymph%= ±3.0%, —; mono%= ±2.0%, —; neut%= ±3.0%, —; eos%= ±1.0%, —; baso%= ±1.0%, —	not available in NCCLS H-20A format
Interfering substances: • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	unusual RBC abnormalities that resist lysing, NRBC, fragmented WBC, unlysed particle >35 fL, large PLT very high WBC, high concentration of very large PLT, autoagglutinins  MCV and Hct: very high WBC, high concentration of large PLT, autoagglutinins  very small RBCs and WBC fragments may cause no fit  very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing	NRBCs, PLT clumps, large PLTs, lyse-resistant RBCs  cold agglutinins, PLT clumps, WBC overlinearity  Hct: lipemic samples, high WBC, cold agglutinins  RBC and WBC fragments  elevated WBC, lipemia lyse-resistant RBCs, NRBCs, lipemia
Interfering substances: differential		
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed	gender-specific printout 75/75 as dictated by your lab procedures, local, or national regulations primary/RBC, WBC, Hb, MCV, PLT, MPV not specified/once per day 125 µL/185 µL/50 µL predilute/0.5 mL	yes 60/60; 80/80 not specified by time open or closed/RBC, WBC, Hb, Hct, PLT not specified/none 30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC differential/53 µL for CBC differential/varies by tube size
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes (multiple sizes and styles) no yes no	yes (multiple sizes) no yes no
If automatic slidemaker available, No. installed/list price	—	—
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 5,000 samples 5,000 samples 5,000 samples yes yes yes yes no yes user or vendor yes, through a selective batch process four colors/cell types colors without thresholds no	yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes no yes user or vendor yes, through user-defined criteria no yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	RS-232, proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, DL2000 enhanced QC, data archiving, common database, delta checking, patient results, and graphics	proprietary; proprietary ASTM numeric and flag results, histograms and differential plots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, DL2000, Command Central enhanced QC, data archiving, common database, optional data management extensive decision rules, delta checking, patient results, and graphics available, centralized management of all instruments no Codabar, codes 39 and 128, interleaved 2 of 5, EAN 8 and 13 yes
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	— Codabar, codes 39 and 128, interleaved 2 of 5, NW7 no	no Codabar, codes 39 and 128, interleaved 2 of 5, EAN 8 and 13 yes
Time required for maintenance by lab personnel	none	none
Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	no — yes/no no	yes — yes/no no
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	VCS technology; low review rate; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single-sample models	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

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

\* linearity stated for Ac•T 5diff CP

## Hematology analyzers

Part 7 of 14	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
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Pentra 60C+ Hematology Analyzer 2000/2000/85 >350/>600/\$45,476	Pentra XL 80 2004/2003/31 >200/>900/\$73,826
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, % neut, mono, lymph, eos, baso): • Laboratory  • Flags	standard menu (left) plus: RDW, MPV  atyp. lymph, atyp. lymph %, LIC, LIC %  operator selectable flagging	standard menu (left) plus: automatic dilution of overrange results (WBC × 3, RBC/hgb/PLT × 2), RDW, MPV atyp. lymph, atyp. lymph%, LIC, LIC%  operator selectable flagging
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only	— — — PCT, PDW, ATL, LIC	— — — PCT, PDW, ATL, LIC
Tests unique to analyzer	—	automatic dilution protocol
Differential method(s) used	DHSS technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement	DHSS technology combining cytochemistry, focused flow impedance, and light absorbance
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	0–120/0–8 0–24/0–1,900 0–67 (Hct)	0–120/0–8 0–24/0–1,900 (>2 g/dL Hb) 0–67 (Hct)/0–2,800 (<2 g/dL Hb)
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<2 percent/<2 percent <1 percent/<5 percent <2 percent (Hct)	<2 percent/<2 percent <1 percent/<5 percent <2 percent (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	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=0.96, —; eos% r=0.89, —; baso% r=0.54, —
Interfering substances: • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	NRBCs, PLT clumps, lyse-resistant RBCs  cold agglutinins  Hct: extreme leukocytosis  microcytes, PLT clumps  extreme lipemia/leukocytosis	NRBCs, PLT clumps, lyse-resistant RBCs  cold agglutinins  Hct: extreme leukocytosis  microcytes, PLT clumps  extreme lipemia, leukocytosis
Interfering substances: differential	NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration	yes 60/60 six months	yes 80/80 six months
• Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed	closed-open/WBC, RBC, Hb, Hct, PLT, MPV per CLIA standards/none 30 µL for CBC and 53 µL for CBC and differential/30 µL for CBC & 53 µL for CBC and differential/—	open, closed/WBC, RBC, Hb, Hct, PLT, MPV per CLIA standards/none 30 µL for CBC/53 µL for CBC and differential/0.5 mL
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes (multiple sizes) yes yes yes	yes (autoloader 13 × 75 mm; closed tube 16 sizes and micro) yes yes yes
If automatic slidemaker available, No. installed/list price	—	—/—
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes, with MultiLink Data Manager MultiLink Data Manager; 100,000 MultiLink Data Manager unlimited with backup MultiLink Data Manager unlimited with backup yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes, with MultiLink Data Manager MultiLink Data Manager; 100,000 MultiLink Data Manager unlimited with backup MultiLink Data Manager unlimited with backup yes yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	ASTM 1394 and 1238, HL7, IEEE MIB numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, LIS to instrument—broadcast yes — yes (MultiLink) enhanced QC, data archiving with Data Manager, autovalidation is used on MultiLink Data Manager; extensive library of validation criteria, delta checking, ability to connect multiple analyzers to one PC	proprietary, ASTM 1394 and 1238, HL7, IEEE MIB numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast — — yes (MultiLink) enhanced QC, data archiving, data collation from multiple instruments, autovalidation is used on MultiLink Data Manager; extensive library of validation criteria, delta checking, ability to connect multiple analyzers to one PC yes Codabar, codes 39 and 128, ASTM, interleaved 2 of 5 yes
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	no Codabar, codes 39 and 128, ASTM, interleaved 2 of 5 yes	yes yes yes
Time required for maintenance by lab personnel	weekly: 15 minutes	weekly: 15 minutes
Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	yes 24 hours yes/yes yes, with Data Manager	yes 24 hours no/yes yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	reliable five-part WBC differential technology—MTBF more than 200 days; small footprint; small sample size of 53 µL	compact five-part differential instrument with autoloader and autodilution capability, auto rerun feature, autovalidation

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

## Hematology analyzers

Part 8 of 14	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 First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Pentra DX120 2005/2004/6 >20/>400/\$199,500	Advia 120 Hematology System 1998/1998/— >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); • Laboratory  • Flags  FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only  Tests unique to analyzer	standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV  LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%, RETH%, IMR%, MRU, MFI%, CRC%  —  — — — PCT, PDW, ATL, LIC, IMG, IML, IMM  —	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, Chr, CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellular Hgb %: hypo, hyper, macro, micro; calc. Hb, MPXI; %: blasts, PMN, MN; large PLT count; RBC fragment count; RBC ghost count; CSF: WBC, RBC, three-part differential; body fluids: TNC, RBC 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  — — IRF, MPC, MPM CSF, eos  CHCM, HDW, Chr, CHCMr, MPC, MPM; CSF: WBC RBC, MN, PMN, neut, lymph, mono
Differential method(s) used  Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet • Hemoglobin Interfering substances: differential	cytochemistry (chlorazol black E) and absorbance  0–150/0.5–8.1 2–25/0–2,000 0–80 (Hct) <2 percent/<2 percent <1 percent/<5 percent <2 percent (Hct) neut% r=0.99, —; lymph% r=0.98, —; mono% r=0.92, —; eos% r=0.97, —; baso% r=0.71, — NRBCs, PLT clumps, lyse-resistant RBCs  cold agglutinins Hct: extreme leukocytosis microcytes, PLT clumps extreme lipemia, leukocytosis  NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	perox–peroxidase cytochemistry staining with light scatter and absorption; baso–cytochemistry stripping with two-angle laser light scatter 0.02–400/0–7.0; CSF WBC 0–5,000/μL; CSF RBC 0–1,500/μL 0–22.5 /5–3,500 30–180 (MCV) 2.7 percent/1.2 percent 0.93 percent/2.93 percent 0.78 percent (MCV) neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6 incomplete RBC lysis (perox only)  cold agglutinins, extreme sickle cell none none high WBC, lip., extremely high bilirubin, interfere with cyanmethemoglobin only, none with direct cellular Hb (CHCM) incomplete lysis of RBCs, complete myeloperoxidase deficiency
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration  • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed  Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep  If automatic slidemaker available, No. installed/list price	yes 120/120 six months  open, closed/WBC, RBC, Hb, Hct, PLT, MPV per CLIA standards/none 130 μL/200 μL/1 mL  yes yes yes, open mode yes  —/—	yes 120/120 six months  open, closed, autosampler/all measured parameters once per shift/not required 157 μL/157 μL/<300 μL (tube size dependent)  yes (2, 3, 5, 7 mL—all sizes—open tube) yes yes yes
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes, with MultiLink Data Manager MultiLink Data Manager; 100,000 MultiLink Data Manager unlimited with backup MultiLink Data Manager unlimited with backup yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features  Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	proprietary, ASTM 1394 and 1238, HL7, IEEE MIB numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast  — — yes (MultiLink) enhanced QC, data archiving, data collation from multiple instruments, auto-validation is used on MultiLink Data Manager; extensive library of validation criteria, delta checking, ability to connect multiple analyzers to one PC yes Codabar, codes 39 and 128, ASTM, interleaved 2 of 5 yes	proprietary (Spec 79) numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics and orders no online documentation yes (CentralLink) enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated differential pad, remote diagnostics, remote workstations LabCell (Siemens) Codabar, codes 39 and 128, ASTM, interleaved 2 of 5 yes
Time required for maintenance by lab personnel  Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	weekly: 15 minutes  yes 24 hours no/yes yes	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes  yes territory dependent yes/no yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, autovalidation	unique 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

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



## Hematology analyzers

Part 9 of 14	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
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Advia 2120 Hematology System 2004/2004/— >200/>900/\$225,000	Advia 2120i 2008/2008/130 >150/>400/\$225,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, % neut, mono, lymph, eos, baso): • Laboratory  • Flags  FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, Chr, CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono % 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 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 — MPC, MPM IRF, CSF, eos CHCM, HDW, Chr, CHCMr, cellular Hgb, MPC, MPM, 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 %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 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 — MPC, MPM IRF, CSF eos CHCM, HDW, Chr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono
Differential method(s) used  Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet • Hemoglobin Interfering substances: differential	peroxidase WBC—peroxidase cytochem. staining with light scatter and absorption; baso—cytochem. stripping with 2-angle laser light scatter 0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500 0–22.5/5–3,500 30–180 (MCV) 2.7 percent/1.2 percent 0.93 percent/2.93 percent 0.78 percent (MCV) neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6 incomplete RBC lysis (peroxidase only) cold agglutinins, extreme sickle cell — extreme lipemia, high WBC, extreme high bilirubin interference w/ colorimetric Hb only, none with cellular Hb incomplete RBC lysis, complete myeloperoxidase deficiency	peroxidase WBC: peroxidase cytochem. staining w/ light scatter and absorption; baso: cytochem. stripping w/ two-angle laser light scatter 0.02–400 CSF: 0–5,000/0–7.0 CSF: 0–1,500 0–22.5/5–3,500 30–180 (MCV) 2.7 percent/1.2 percent 0.93 percent/2.93 percent 0.78 percent (MCV) 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 incomplete RBC lysis (peroxidase only) cold agglutinins, extreme sickle cell none none extreme lipemia, high WBC, extreme high bilirubin—interference w/ colorimetric Hgb only, none with cellular Hgb incomplete RBC lysis, complete myeloperoxidase deficiency
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed  Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep  If automatic slidemaker available, No. installed/list price	yes 120/120 six months autosampler, closed, open/all measured parameters once per shift/not required 175 µL/175 µL/<300 (tube size dependent)  yes (2, 3, 5, 7 mL—all sizes open) yes yes if integrated to Advia Autoslide  Advia Autoslide, —/\$98,000	yes 120/120 six months auto sampler, closed, open/all measured parameters once per shift/not required 175 µL/175 µL/<300 (tube size dependent)  2, 3, 5, 7, mL closed—all tube sizes open yes yes yes  Advia Autoslide, —/\$98,000
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes no 10,000 10,000 10,000 yes yes yes yes yes yes yes user or vendor yes yes yes yes	yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features  Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	proprietary 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)  no online documentation yes (Centralink) enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated differential pad, remote diagnostics, remote workstations LabCell (Siemens) Codabar, codes 39 and 128, interleaved 2 of 5 —	proprietary (instrument or vendor specific) numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics and orders  no Web site: online documentation yes, Centralink enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated differential pad, remote diagnostics, remote workstations LabCell (Siemens) Codabar, codes 39 and 128, ASTM, interleaved 2 of 5 yes
Time required for maintenance by lab personnel  Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	weekly: 15 minutes; monthly: 15 minutes  yes territory dependent yes/no yes	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes  yes territory dependent yes/no yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	unique 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

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

## Hematology analyzers

Part 10 of 14	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Sysmex XT-4000i 2010/2009/— 32/>150/\$195,700	Sysmex poch-100i 2004/2003/103 >800/—/\$18,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso): • Laboratory  • Flags	standard menu (left) plus: IG% and #, retic % and #, IRF, RET-He, PLT-O, BF: RBC/WBC/TC/two-part differential —  PLT clumps, PLT ABN distribution, blast, imm grans, left shift, atyp lymph, ABN lymph/blasts, NRBC, RBC lyse resistance, RBC ABN distribution, RBC agglutination, turbidity — — — reticulocyte hemoglobin, immature reticulocyte fraction, reportable immature granulocyte # and %, PLT-O, BF: RBC/WBC/TC/two-part differential	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, lymph, MXD  RDW-SD, RDW-CV, MPV  histogram error flags; WBC, RBC, PLT  — — — —
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	— — — — reticulocyte hemoglobin, immature reticulocyte fraction, reportable immature granulocyte # and %, PLT-O, BF: RBC/WBC/TC/two-part differential	— — — — —
Differential method(s) used	fluorescent flow cytometry	direct current (DC)
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	0–440/0–8 0–25/0–5,000 0–60 (Hct)	1.0–99.9/0.3–7.0 0.1–25.0/10–999 10–60 Hct
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<=3.0 percent/<=1.5 percent <=1.5 percent/<=4.0 percent <=1.5 percent (Hct)	<=3.5 percent/<=2.0 percent <=1.5 percent/<=6.0 percent <=2.0 percent Hct
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	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=0.98, LYM% R=0.99, MXD % R=0.75, NEUT# R=1.00, LYM# R=1.00, MXD# R=0.90
Interfering substances: • WBC  • RBC • MCV or Hct  • Platelet  • Hemoglobin	cold agglutinin, severe microcytosis, fragmented RBC, leukocytosis Hct: cold agglutinin, fragmented RBC, spherocytosis, leukocytosis (lymphocytes>100,000/μL) PLT aggregation, pseudothrombocytopenia, giant platelets, microcytosis, cryoglobulin leukocytosis (lymphocytes>100,000/μL), lipemia, abnormal protein	lyse-resistant RBC, cold agglutinins/cryoglobulins, PLT aggregation, NRBC  cold agglutinins, microcytosis (severe), fragmented RBCs cold agglutinins, fragmented RBCs, leukocytosis (>100,000/uL)  PLT aggregation, giant PLTs, microcytic RBCs, fragmented RBCs  lipemia (severe), abnormal protein, leukocytosis (>100,000/uL)
Interfering substances: differential	lyse-resistant RBC	—
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed	yes 100/100 once by year by FSR open-closed/WBC, PLT, RBC, HGB, Hct per regulatory requirements/none 85 μL/150 μL/1 μL	yes 30/30 per regulatory agency requirements primary, whole blood mode/WBC, RBC, HGB, Hct, PLT per regulatory agency requirements/none 15 μL/15 μL/15 μL
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes, diameter 12–15 mm; length <=75 mm no yes no	yes, diameter: 13–15 mm; height: <=75 mm microtubes yes yes no
If automatic slidemaker available, No. installed/list price	—	—
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes 100 samples 100 samples 100 samples yes yes yes yes yes no yes no no yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	ASTM 1394 and 1238 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics and orders yes contact vendor yes, Sysmex WAM (work area manager) enhanced QC, data archiving, data collation from multiple instruments, wide area network capabilities	RS-232C numeric and flag results, histograms and scatterplots, patient demographics, patient orders, host query for patient demographics and orders yes contact vendor yes, Antek enhanced QC, data archiving
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	— Codabar, codes 39 and 128, ASTM, interleaved 2 of 5, ITF, NW7 yes	— codes 39 and 128, ASTM, ITF, NW7, JAN-8 and 13 yes
Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	daily: <3 minutes yes <24 hours yes/no yes	daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes yes <24 hours; depot service no/no yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	unique 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 Sysmex X series analyzers; simplified operations with extended linearities, high-throughput, remote monitoring capabilities	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

## Hematology analyzers

Part 11 of 14	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Sysmex KX-21N 2001/1999/99 >2,000/—/\$26,780	Sysmex XE-5000 2008/2008/>125 >450/>1,500/\$265,122
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, % neut, mono, lymph, eos, baso): • Laboratory • Flags	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, % neut, lymph, MXD  RDW-SD, RDW-CV, MPV histogram error flags; WBC, RBC, PLT	standard menu (left) plus: NRBC % retic %, RDW-SD, RDW-CV, IRF, PLT-O, HPC#, MPV, IG%, IG#, RET-He, IPF  — PLT clumps, PLT ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blast, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity  — — — — reticulocyte hemoglobin, immature platelet fraction, hematopoietic progenitor cell, immature reticulocyte fraction, reportable immature granulocyte %, RBC/WBC/TC/two-part differential
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	— — — — —	— — — — —
Differential method(s) used	direct current (DC)	fluorescent flow cytometry, RF/DC detection method
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	1.0–99.9/0.3–7.0 0.1–25.0/10–999 10–60 Hct	0–440/0–8 0–25/0–5,000 0–75 (Hct)
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<=3.5 percent/<=2.0 percent <=1.5 percent/<=6.0 percent <=2.0 percent Hct	<3 percent/<1.5 percent <1.0 percent/<4.0 percent <1.5 percent (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	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=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922
Interfering substances: • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	cold agglutinin, PLT aggregation, erythroblastosis, NRBC, cryoglobulins  cold agglutinin, severe microcytosis, fragmented RBC, leukocytosis (>100,000/ $\mu$ L) Hct: cold agglutinin, leukocytosis (>100,000/ $\mu$ L), abnormal red cell fragility, spherocytosis pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs leukocytosis (>100,000/ $\mu$ L), lipemia, abnormal protein	cold agglutinins, PLT aggregation, nucleated RBCs, cryoglobulin, lyse-resistant RBCs cold agglutinins, severe microcytosis, fragmented RBCs, large number giant PLTs, in vitro hemolysis Hct: cold agglutinins, leukocytosis, ABN red cell fragility, spherocytosis  pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs lipemia, ABN proteins, leukocytosis (>100,000/ $\mu$ L) lyse-resistant RBCs
Interfering substances: differential	—	—
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes 60/60 per regulatory agency requirements primary, whole blood mode/WBC, RBC, HGB, Hct, PLT per regulatory agency requirements/none 50 $\mu$ L/—/— yes yes yes no	yes 150/150 once per year by FSR open, closed, capillary/WBC, RBC, Hb, Hct, PLT 2 levels once every 24 hours (minimum per CLIA)/none 130 $\mu$ L/200 $\mu$ L/1 mL yes no yes yes (with Alpha or HST upgrade)
If automatic slidemaker available, No. installed/list price	—	>1,200/price depends on configuration
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 300 samples 300 samples 300 samples yes yes yes yes yes yes yes yes yes no no yes yes	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface	RS-232C numeric and flag results, histograms and scatterplots, host query for patient demographics and orders	ASTM 1394, TCP-IP, ASTM E1381 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 results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	yes contact vendor no —	yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, rules setting
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	— codes 39 and 128, ASM, ITF, NW-7, JAN, UPC-A, UPC-E, EAN13, EAN8 yes	Roche Diagnostics, and Labotix, A & T, Thermo, IDS Codabar, codes 39 and 128, ASTM, interleaved 2 of 5, ITF, NW7, EAN 8 and 13 —
Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes yes <24 hours no/no yes	daily: <3 minutes yes <24 hours yes/no yes, also via Internet
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	automatic floating discriminators	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 Sysmex X series analyzers

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

## Hematology analyzers

Part 12 of 14	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Sysmex XE-2100 1999/—/>>390 1,325/>>5,000/\$240,000	Sysmex XE-2100D 2004/2004/>>65 190/>>790/\$200,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso):  • Laboratory • Flags	standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, PLT-0, HPC#, MPV, IG%, IG#, RET-He, IPF  — PLT clumps, RBC agglut, turbidity, WBC ABN scattergram, RBC ABN distribution, PLT ABN distribution, RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph./blast., reticulocyte ABN scattergram — P-LCR, PCT, PDW HPC#, IG%, IG#, RET He, IPF	standard menu (left) plus: RDW-SD, RDW-CV  — PLT clumps, PLT ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blast, RBC ABN distribution, RBC lyse resistance, RBC agglutinins, turbidity — — P-LCR, PCT, PDW optional: IG% & IG#
Differential method(s) used Linearity: Precision: Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation Interfering substances: Interfering substances: differential	fluorescent flow cytometry, RF/DC detecting method 0-440/0-8 0-25/0-5,000 0-75 (Hct) <3 percent/<1.5 percent <1.0 percent/<4.0 percent <1.5 percent (Hct) 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 cold agglutinin, PLT aggregation, nucleated RBCs, cryoglobulin, lyse-resistant RBCs cold agglutinins, severe microcytosis, fragmented RBCs, large No. giant PLTs, in vitro hemolysis Hct: cold agglutinins, leukocytosis, ABN red cell fragility, spherocytosis pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs lipemia, ABN proteins, leukocytosis (>100,000/ $\mu$ L) lyse-resistant RBCs	fluorescent flow cytometry 0-440/0-8 0-25/0-5,000 0-75 (Hct) <3 percent/<1.5 percent <1.0 percent/<4.0 percent <1.5 percent (Hct) 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 cold agglutinins, PLT aggregation, cryoglobulin, lyse-resistant RBCs, NRBCs cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis Hct: cold agglutinins, ABN red cell fragility, spherocytosis, leukocytosis pseudothrombocytopenia, PLT aggregation, increased microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/ $\mu$ L) lyse-resistant RBCs
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed	yes 150/150 once per year by FSR open, closed, capillary/WBC, RBC, Hb, Hct, PLT per requirements/none 130 $\mu$ L/200 $\mu$ L/1 mL	yes 150/150 once per year by FSR open, closed, capillary/WBC, RBC, Hb, Hct, PLT per CLIA requirements/none 130 $\mu$ L/200 $\mu$ L/1 mL
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price	yes no yes yes (with Alpha or HST upgrade) >1,000/price depends on configuration	yes no yes yes, with Alpha or HST upgrade >1,000/price depends on configuration
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features  Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	RS-232C/TCP IP numeric and flag results, histograms and scatterplots, patient demographics, orders  yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, multiple sites on automation platform Codabar, codes 39 and 128, interleaved 2 of 5, ITF, NW7, EAN 8 and 13 yes	RS-232C/TCP IP numeric and flag results, histograms and scatterplots, patient demographics, orders  yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, multiple sites on automation platform Codabar, codes 39 and 128, ASTM, interleaved 2 of 5, ITF, NW7, EAN 8 and 13, ISBT yes
Time required for maintenance by lab personnel  Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	daily: <3 minutes  yes <24 hours yes/no yes, also via Internet	daily: <3 minutes  yes <24 hours yes/no yes, also via Internet
Acquisition program based on cost-per-reportable result	yes	yes
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 Sysmex X series analyzers	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

Part 13 of 14	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Sysmex XE-Alpha N/HST-N 2000/—/>>160 >725/1,300/\$360,000–\$1,000,000	Sysmex XT-2000i 2002/2001/>>235 >900/>>5,200/\$149,500
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, % neut, mono, lymph, eos, baso):  • Laboratory • Flags	standard menu (left) plus: NRBC%&#, retic%&#, RDW-SD, RDW-CV, IRF, PLT-O, HPC#, MPV, IG%, IG#, RET-He, IPF  — user-defined, all-inclusive	standard menu (left) plus: retic %&#, IRF, PLT-O, MPV, RDW-SD, RDW-CV, reticulocyte hemoglobin, immature granulocytes %&#  — PLT clumps, PLT ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglutinins, turbidity, NRBC, body fluids
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	— — — P-LCR, PCT, PDW NRBC, HPC#, IG%, IG#, RET-He, immature platelet function (IPF)	— — — — PLT-O, immature granulocytes (IG) %&#, reticulocyte hemoglobin (RET-He)
Differential method(s) used	fluorescent flow cytometry, RF/DC detecting method	fluorescent flow cytometry
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) • MCV (fL) or Hct (%)	0–440/0–8 0–25/0–5,000 0–75 (Hct)	0–310/0–8 0–25/0–5,000 0–60 (Hct)
Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct	<3 percent/<1.5 percent <1.0 percent/<4.0 percent <1.0 percent (Hct)	≤3.0 percent/≤1.5 percent ≤1.5 percent/≤4.0 percent ≤1.5 percent (Hct)
Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922	neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=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  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	cold agglutinins, PLT aggregation, nucleated RBCs, cryoglobulins, lyse-resistant RBCs cold agglutinins, severe microcytosis, fragmented RBCs, large No. giant PLTs, in vitro hemolysis Hct: cold agglutinins, leukocytosis, ABN red cell fragility, spherocytosis  pseudothrombocytopenia, PLT aggregation, increased microcytosis, megalocytic PLTs lipemia, ABN proteins, leukocytosis (>100,000/μL)	cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis  Hct: cold agglutinins, ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, PLT aggregation, increased microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL)
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration	yes 150/150 per analyzer on automation system once per year by FSR	yes 80/80 once per year by FSR
• Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed	open, closed, capillary/WBC, RBC, Hb, Hct, PLT two levels once every 24 hours (minimum CLIA)/none 130 μL/200 μL/1 mL	open, closed, capillary/— per CLIA requirements/none 85 μL/150 μL/1 mL
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes no yes yes	yes yes, XT-V product yes no
If automatic slidemaker available, No. installed/list price	>1,700/\$250,000	—
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 10,000 samples 10,000 samples; 20,000 orders 10,000 samples; two years plus, with optional decision logic software yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface  LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	RS-232C/TCP IP numeric and flag results, histograms and scatterplots, patient demographics, orders yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, multiple sites	RS-232/TCP-IP, ASTM numeric and flag results, histograms and scatterplots, patient demographics, orders yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	Roche, Labotix, IDS, A&T, Thermo engen Codabar, codes 39 and 128, interleaved 2 of 5, ITF, NW7, EAN 8 and 13 yes	— Codabar, codes 39 and 128, interleaved 2 of 5, ITF, NW7, EAN 8 and 13 yes
Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	daily: <three minutes (operator time) yes <24 hours yes/no yes, also via Internet	daily: <three minutes yes <24 hours yes/no yes, also via Internet
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	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	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

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

## Hematology analyzers

Part 14 of 14	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Tammy Kutz communications@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2009 No. units installed in U.S./outside U.S./List price	Sysmex XT-1800i 2002/2001/>125 >900/4,600/\$128,750	XS-1000i and XS-1000i AutoLoader (20 sample autoloader option) 2006/2005/>320 >1,080/>6,000/\$85,000 (XS-1000i) \$95,000 (AutoLoader)
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, %&# neut, mono, lymph, eos, baso): • Laboratory • Flags  FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	standard menu (left) plus: MPV, RDW-SD, RDW-CV, immature granulocytes %&# — PLT clumps, PLT ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglutinins, turbidity, NRBC, body fluids — — — immature granulocytes (IG%&#)	standard menu (left) plus: MPV, RDW-SD, RDW-CV — PLT clumps, PLT ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglutinins, turbidity, NRBC — — IG% research screen —
Differential method(s) used	fluorescent flow cytometry	fluorescent flow cytometry
Linearity: • WBC count (10 <sup>9</sup> /L)/RBC count (10 <sup>12</sup> /L) • Hemoglobin (g/dL)/platelet (10 <sup>9</sup> /L) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated differential compared with manual differential (per CLSI H-20A), regression equation	0-310/0-8 0-25/0-5,000 0-60 (Hct) ≤3.0 percent/≤1.5 percent ≤1.5 percent/≤4.0 percent ≤1.5 percent (Hct) 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	0-400/0-8 0-25/0-5,000 0-60 (Hct) —/— —/— — neut% r=0.96, y=0.9074x+3.8948; lymph% r=0.97, y=0.9017x+2.4817; mono% r=0.78, y=0.8626x+3.5938; eos% r=0.94, y=0.9076x+0.3651; baso% r=0.29, y=0.1538x+0.298
Interfering substances: • WBC  • RBC  • MCV or Hct  • Platelet  • Hemoglobin	cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs  cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis  Hct: cold agglutinins, ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, PLT aggregations, increased microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL)	cold agglutinins, PLT aggregation, cryoglobulins, lyse-resistant RBCs, NRBCs  cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis  Hct: cold agglutinins, ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, PLT aggregation, increased microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL)
Interfering substances: differential	lyse-resistant RBCs	lyse-resistant RBCs
Age- and sex-specific reference ranges Maximum CBCs per hour/Maximum CBCs and differentials per hour Recommended average frequency of calibration • Modes calibrated/parameters calibrated Frequency of blood/latex controls Minimum specimen volume open/closed/Sample dead volume closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	yes 80/80 once per year by FSR open, closed, capillary/— per CLIA requirements/none 85 μL/150 μL/1 mL yes yes, XT-V product yes no	yes 60/60 once per year closed and capillary/— per CLIA requirements/none 20 μL/20 μL/1.0 mL yes (up to 85 mm height) no yes no
If automatic slidemaker available, No. installed/list price	—	—
Archives patient data for later comparison Patient-specific archiving Maximum archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images and CBC data printed as one report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirmatory testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result information displayed	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes	yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes yes
LIS interface formats supported Information transferred on LIS interface	RS-232C/TCP-IP, ASTM numeric and flag results, histograms and scatterplots, patient demographics, orders	proprietary, ASTM 1394, TCP-IP numeric and flag results, histograms and scatterplots, patient demographics, orders
LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data management or collation system • Software features	yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, multiple sites	yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, multiple sites
Interface available or planned to automate specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	— Codabar, codes 39 and 128, interleaved 2 of 5, ITF, NW7, EAN 8 and 13 yes	— Codabar, codes 39 and 128, ASTM, interleaved 2 of 5, NW7, EAN 8 and 13, ITF yes
Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Manufacturer can perform diagnostics via modem	daily: <three minutes yes <24 hours yes/no yes, also via Internet	daily: three minutes; weekly: none; monthly: nine minutes yes <24 hours yes/no yes, also via Internet
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features (supplied by company)	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	standardized technology, reagents, controls, and operations to 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

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