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Hematology analyzers

ricinatology analyzers		
Part 1 of 13	Abbott Hematology David Overcash David.Overcash@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 2008 No. units installed in U.S./outside U.S./list price	CELL-DYN Ruby* 2006/2006/— >250/>400/\$185,000	
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso): • Laboratory • Flags	standard menu (left) plus: MPV, RDW, RETIC #&% #&% for bands, IG, blast, var lymph NRBC, FWBC, NWBC, RRBC, band, IG, blast, variant lymph, RBC morph., DFLT, MCHC, LRI, URI, LURI, ATYPDEP, high/low interp. message, WBC	
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only	none none none	
Tests unique to analyzer	atypical depolarization flag	
Differential method(s) used	MAPSS (Multi-Angle Polarized Scatter Separation)	
Linearity: • WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) • Hemoglobin (g/dL)/platelet (10 ⁹ /L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet • Hemoglobin	0.00–246 × 10³/µL/0.00–7.50 × 10⁶/µL 0.00–25.0 g/dL/0.00–3,000 × 10³/µL 58–139 fL: (MCV) 2.4%/1.8% 1.4%/3.8% 0.8% (MCV) neut% r=0.983, slope=0.97, y=-1.98; lymph r=0.921, slope=0.95, y=0.94; mono r=0.711, slope=1.10, y=1.93; eos r=0.952, slope=1.04, y=0.01; baso r=0.146, slope=0.18, y=1.22 fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin elevated WBC, increased numbers of giant Plt, autoagglutination, in vitro hemolysis MCV: elevated WBC, hyperglyc., in vitro hemolysis, increased No. of giant Plts WBC fragments, in vitro hemolysis, microcytic RBC, cryofibrinogen, cryoglobulins, Plt clumping, increased No. of giant Plt elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo	
Interfering substances: differential	hemolysis), lytic-resistant RBC fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, PIt clumps, cryofibrinogen, cryoglobulin, paraproteins	
Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated	yes up to 84/up to 84 6 months verification open or closed/WBC, RBC, Hgb, MCV, Plt	
Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price	per local regulatory requirements/— 150 μL/230 μL/1.2 mL yes (13 × 75 mm) no no/\$125,000	
Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed	yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes yes yes yes no yes user or vendor — yes 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	
LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features	no — yes enhanced QC, data archiving, data collation from multiple instruments	
Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	— Codabar, codes 39 and 128, interl. 2 of 5, 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 Mftr. can perform diagnostics via modem	daily: 30 sec; weekly: 5 min; monthly: 10 min yes — yes/no yes	
Acquisition program based on cost-per-reportable result	yes	
Distinguishing features	touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode; rules-based result annotations *please see the corresponding operator's manual for product labeling, including warnings, limitations, and precautions	

including warnings, limitations, and precautions

Fig. 12 in 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	18 / CAP TODAY	Hematology analyzers	December 2009
Part of 12 12 12 12 12 13 13 13		riematology analyzers	
Reference of the Control Contr	Part 2 of 13	David Overcash David.Overcash@Abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535	Karen Semiao karen.semiao@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 408-567-3384
Selection (C. A. Co. Co. C. A. Selection (C. A. C.	First year installed in U.S./outside U.S./No. of units sold in 2008	2005/2005/—	2009/2008/0
The control amonable and materials for consistent and production of the control o	MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso): • Laboratory • Flags	%&#, CD4T %&#, CD8T %&#, 4/8 — band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clmp, ASYM, FP, CD61 agg., clot detected during aspiration, short sample</td><td>RDW, MPV — dispersional data alerts, suspect measurand flags and count invalidation flags</td></tr><tr><td> April 1995 Control of Control</td><td>Tests not available but submitted for clearance Tests in development For research use only</td><td>none optical RBC morphology none</td><td>none none</td></tr><tr><td> Clament Will Count of Policy Nation Coun</td><td></td><td>, , , ,</td><td></td></tr><tr><td>## 1880 ##</td><td>Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation</td><td>$\begin{array}{l} 0.4-250.0\times10^3~\mu\text{L}/~0.22-7.50\times10^6~\mu\text{L}\\ 1.0-24.8~g/d\text{L}~(cyanide~free)/11.0-2,000.0\times10^3~\mu\text{L}\\ 37.0-179~\text{fL}~(\text{MCV})\\ \leq 2.7\%/\leq 1.5\%\\ \leq 1.0\%/\leq 4.0\%\\ \leq 1.0\%~(\text{MCV})\\ \text{neut}\%~r=0.942~\text{slope}~0.947~\text{y}=0.446;~\text{lym}\%~r=0.936~\text{slope}=0.943~\text{y}=2.811;~\text{mono}\%\\ r=0.623~\text{slope}=1.057~\text{y}=0.851;~\text{eos}\%~\text{r}=0.446~\text{slope}=1.024~\text{y}=0.288;~\text{baso}\%\\ r=0.232~\text{slope}=0.257~\text{y}=0.350 \end{array}$</td><td>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% (Hct)/48.8–115 fL (MCV) 3.5% (95% confidence limit)/2.0% (95% confidence limit) 2.1% (95% confidence limit)/6.1% (95% confidence limit) 1.7% Hct (95% confidence limit)/0.8% MCV (95% confidence limit) —/—</td></tr><tr><td>## ONC and projection of the p</td><td></td><td>cryoglob., cryofibr., frag. WBC, nRBC</td><td>cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/</td></tr><tr><td>**Nemoglobin*** **Nemoglobin** **Interferring substances: differential** **Interferring substances: differential**</td><td></td><td>hyperglycemia</td><td>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</td></tr><tr><td>Interfuring substances differentials Age—and sex-specific reference ranges Age—and sex-specific reference r</td><td></td><td>frag., WBC frag., PIt satellitism</td><td>cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin platelet clumping, platelet satellitosis carboxyhemoglobin (>10%), cryoglobulin, cryofibrinogen, hemolysis (in vivo)</td></tr><tr><td>Nax. CBCs of lifts, per hr Recommended expert requency of Califac per hr Recommended expert requency of Califac controls Max special calibrated presency of Califac controls Max special calibrated presence calibrated presentation calibrated presents calibrated presentation calibrated presents calibrated</td><td>Interfering substances: differential</td><td>see WBC</td><td>monoclonal proteins platelet aggregates, NRBCs, giant platelets, cryoglogulins, incomplete lysis of RBC, small lymphocytes, fibrin clots, shift in WBC cell distribution due to EDTA</td></tr><tr><td>Frequency of bloodinates controls Min. specimens of Lipe Sampling supported Table Sampling Sample Sampling Sample Sampling Sampling</td><td>Max. CBCs per hr/max. CBCs & diffs. per hr</td><td>106/106</td><td>60/60 scheduled calibration of the CELL-DYN Emerald must conform to the guidelines</td></tr><tr><td>Patient-specific archiving Memory capacity—numeric results—No. specimens Memory capacity—numeric results—No. specimens Memory capacity—numeric results—No. specimens 10,000 results 10,000 results 10,000 results 10,000 results 10,000 results on USB and 1,500 results on internal memory 9,000 results on USB and 1,500 results on ISB and 1,</td><td>Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep</td><td>per regulatory requirement/— 117 μL/117 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 yes (flags only)</td><td>per regulatory requirement/— 9.8 µL/—/— yes (open mode) no no</td></tr><tr><td>Max. archived data accessible when system online Memory capacity—Institor/tograms—No. specimens 10,000 results 10,000 results 90,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500 results on Internal memory 00,000 results on USB and 1,500</td><td></td><td>yes</td><td>yes</td></tr><tr><td>Parameters for flags for holding samples are defined by Some results can be transmitted to Lis while others held Scattergram display; cell-specific color yes yes yes considered properties of desired specimen and/or result into displayed with results holding supported information transferred on LIS interface formats supported information transferred on LIS interface with results how labs get LOINC codes to reagent kits opional data mgmt. or collation system software features linterface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A Time required for maintenance tocords Time from communication of problems on no handled to software problems with results how and significant maintenance records Time from communication of problems on no handled to software problems where the contract on no handled to software problems where the contract on no handled to software problems where the contract on no handled to software problems where the contract on no handled to software problems where the contract on no handled to software problems where the contract on no handled to software problems where the contract on no handled to software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software problems where the contract on no handled the software with intuitive icons and minimal layers; please see the corresponding operators manual for product labeling, please see</td><td>Max. archived data accessible when system online Memory capacity—numeric results–No. specimens Memory capacity—histo/cytograms–No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks</td><td>10,000 results 10,000 results 10,000 results yes yes yes yes yes yes</td><td>60,000 results on USB and 1,500 results on internal memory 60,000 results on USB and 1,500 results on internal memory 60,000 results on USB and 1,500 results on internal memory yes yes yes yes</td></tr><tr><td>Information transferred on LIS interface Inumeric and flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders no — — — — — — — — — — — — — — — — — —</td><td>Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold</td><td>yes yes yes</td><td>no no no</td></tr><tr><td>How labs get LOINC codes for reagent kits Optional data mignit, or collation system **Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Codabar, codes 39 and 128, interlace 2 of 5, Chinese post, code 93, EAN8, EAN13, EAN128, IATA, industrial 2 of 5, MSI/Plessey, UK/Plessey, UK/Plessey, Telepen, TriOptic, S-Code, UPC A, UPC E 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 Mftr. can perform diagnostics via modem Acquisition program based on cost-per-reportable result yes four optical and three fluorescent detectors provide mult. scatterplot analysis; 2-D optical platelets avoid interferences; fluorescent analysis or routine hematology analyzer; openFlow MRBCs, and 3-color monoclonal analyzer; openFlow MRBCs, and 3-color monoclonal analyzer; openFlow MRBCs, and 3-color monoclonal analyzer; openFlow MRB bas selections; 'please see the corresponding operator's manual for product labeling, 'please see the corresponding operator's 'please see the corresponding operator's</td><td>Information transferred on LIS interface</td><td>numeric and flag results, instrument to LIS; patient demographics, patient orders,</td><td></td></tr><tr><td>Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Codabar, codes 39 and 128, interl. 2 of 5 Accommodates bar-code placement per CLSI standard Auto2A 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 Mftr. can perform diagnostics via modem Distinguishing features four optical and three fluorescent detectors provide mult. scatterplot analysis or reducilocytes, NRBCs, and 3-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections; "please see the corresponding operator's "plea</td><td>How labs get LOINC codes for reagent kits Optional data mgmt. or collation system</td><td>no — yes enhanced QC, data archiving, data collation from multiple instruments,</td><td>_</td></tr><tr><td>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 Mftr. can perform diagnostics via modem Acquisition program based on cost-per-reportable result Distinguishing features four optical and three fluorescent detectors provide mult. scatterplot analysis; 2-D optical platelets avoid interferences; fluorescent analysis of reticulocytes, NRBCs, and 3-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections; *please see the corresponding operator's daily: 3 min; monthly: 5 min; bi-annually: 10 min yes dependent upon service contract non/no no no 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; *please see the corresponding operator's manual for product labeling,</td><td>Bar-code symbologies read on tube</td><td>none Codabar, codes 39 and 128, interl. 2 of 5</td><td>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</td></tr><tr><td>Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem Acquisition program based on cost-per-reportable result Distinguishing features four optical and three fluorescent detectors provide mult. scatterplot analysis; 2-D optical platelets avoid interferences; fluorescent analysis of reticulocytes, NRBCs, and 3-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections; *please see the corresponding operator's yes dependent upon service contract no/no no no 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; *please see the corresponding operator's manual for product labeling,</td><td>· ·</td><td>-</td><td>•</td></tr><tr><td>Distinguishing features four optical and three fluorescent detectors provide mult. scatterplot analysis; 2-D optical platelets avoid interferences; fluorescent analysis of reticulocytes, NRBCs, and 3-color monoclonal analysis on routine hematology analyzer; NRBCs and 3-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections; *please see the corresponding operator's 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; *please see the corresponding operator's manual for product labeling,</td><td>Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems</td><td>yes — yes/no</td><td>yes dependent upon service contract no/no</td></tr><tr><td>2-D optical platelets avoid interferences; fluorescent analysis of reticulocytes, averages one service call per year; easy to use: system has touchscreen NRBCs, and 3-color monoclonal analysis on routine hematology analyzer; software with intuitive icons and minimal layers; openFlow MAb test selections; *please see the corresponding operator's *please see the corresponding operator's manual for product labeling,</td><td>Acquisition program based on cost-per-reportable result</td><td>yes</td><td>no</td></tr><tr><td></td><td>Distinguishing features</td><td>2-D optical platelets avoid interferences; fluorescent analysis of reticulocytes, NRBCs, and 3-color monoclonal analysis on routine hematology analyzer; OpenFlow MAb test selections; *please see the corresponding operator</td><td>averages one service call per year; easy to use: system has touchscreen software with intuitive icons and minimal layers; *please see the corresponding operator's manual for product labeling,</td></tr></tbody></table>	

Hematol	logy an	alyzers
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Part 3 of 13	Abbott Hematology David Overcash David.Overcash@Abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054	Abbott Hematology David Overcash David.Overcash@Abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054
	800-933-5535 www.abbottdiagnostics.com	800-933-5535 www.abbottdiagnostics.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2008 No. units installed in U.S./outside U.S./list price	CELL-DYN 3700* 1999/1999/— >250/>1,000/\$180,000 SL Model, \$140,000 CS Model	CELL-DYN 3200* 1997/1997/— >600/>1,000/\$165,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV,	standard menu (left) plus: RDW, MPV, RETIC #&%, IRF	standard menu (left) plus: RDW, MPV
MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso): • Laboratory	band, IG, variant lymph, blast, PCT, PDW, NRBC #&% and retic scatter profile	band #&%, IG #&%, variant lymph #&%, blast #&%, PCT, PDW, NRBC #&%
• Flags	suspect populations, band, blast, variant lymph, IG, NRBC, RRBC, NWBC, LRI,	band, IG, variant lymph, blast, NRBC, NWBC, RRBC, FWBC, RBC morph.,
FDA-cleared tests but not clinically released	URI, LURI, RBC morph., FWBC, high/low interp. message, WBC none	high/low interp. message, LRI, URI, LURI, WBC none
Tests not available but submitted for clearance Tests in development	none none	none none
For research use only	none IRF	atypical depolarization flag outside U.S. 3-D optical RBC analysis with advanced MCV measurement
Tests unique to analyzer		
Differential method(s) used Linearity: • WBC count (10 ⁹ /L)/RBC count (10 ¹² /L)	MAPSS (Multi-Angle Polarized Scatter Separation) 0-250 K/μL/0-8 M/μL	MAPSS (Multi-Angle Polarized Scatter Separation) 0-250 K/μL/0-8 M/μL
 Hemoglobin (g/dL)/platelet (10⁹/L) MCV (fL) or Hct (%) 	0–24 g/dL/0–2,000 K/µL 50–200 fL (MCV)	0–25 g/dL/0–1,750 K/μL 34–172 fL (MCV)
Precision: • WBC count/RBC count	≤ 2. 5%/≤1.5̇%	≤2.7%/≤1.5%
Hemoglobin/platelet MCV or Hct	≤1.2%/≤5.0% ≤1.0% (MCV)	≤1.0%/≤4.0% ≤1.0% (MCV)
Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation	neut #&%: ≥0.95, —; lymph #&%: ≥0.94, —; mono #&%: ≥0.86, —; eos #&%: ≥0.84, —; baso #&%: ≥0.73, —	neut #&%: ≥0.95, —; lymph #&%: ≥0.94, —; mono #&%: ≥0.86, —; eos #&%: ≥0.84, —; baso #&%: ≥0.73, —
Interfering substances: • WBC	NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and	NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen,
• RBC	cryofibrinogen, fragile WBCs increased No. giant Plts, autoagglutination, in vitro hemolysis	fragile WBCs elevated WBC count, increased No. giant Plts, autoagglutination, in vitro
, MAV U-1	MCV/ elevated WDC accept increased No. 1914 Disc. 1914 Disc. 1914	hemolysis
MCV or Hct	MCV: elevated WBC count, increased No. giant Plts, hyperglycemia, in vitro hemolysis	MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased No. giant Plts
• Platelet	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt clumps, increased No. giant Plts	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Plts
• Hemoglobin	increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs	elevated WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs
Interfering substances: differential	see WBC	see WBC
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib.	90/90 6 months verification	71/71 6 months verification
. ,		
Modes calibrated/parameters calibrated Frequency of blood/latex controls	open & closed/WBC, RBC, Hb, MCV, Plt as per regulatory requirement/—	open & closed/WBC, RBC, Hb, MCV, Plt, MPV as per regulatory requirement/—
Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported	130 μL/355 μL/1.0 mL yes (13 \times 75 mm)	150 μL/240 μL/1 mL (sample loader) yes
Veterinary capability Microsample capability	yes	no
Prepares microscopic slides automatically or flags problems for	yes yes (flags only)	yes yes
slide prep If automatic slidemaker available, No. installed/list price	—/\$125,000	—/\$125,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving Max. archived data accessible when system online	yes 10,000 results	yes 10,000 results
Memory capacity—numeric results–No. specimens	10,000 results	10,000 results
Memory capacity—histo/cytograms–No. specimens • Stored in conjunction with CBC data	10,000 results yes	10,000 results yes
Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted	yes yes	yes yes
Saved data can be sorted for reprocessing or report transmission Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	no yes	no yes
Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held	user or vendor yes	user or vendor yes
Scattergram display: cell-specific color Histogram display: color with threshold	yes yes	yes yes
Choice of desired specimen and/or result info. displayed	yes	yes
LIS interface formats supported	proprietary	proprietary
Information transferred on LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with results How labs get LOINC codes for reagent kits	no	no
Optional data mgmt. or collation system	yes	yes
Software features Interface avail. or planned to auto. specimen-handling system	enhanced QC, data archiving, data collation from multiple instruments —	enhanced QC, data archiving, data collation from multiple instruments —
Bar-code symbologies read on tube	Codabar, codes 39 and 128, interl. 2 of 5	Codabar, codes 39 and 128, interl. 2 of 5
Accommodates bar-code placement per CLSI standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 30 sec; bi-weekly: 5 min; monthly: 10 min	daily: 30 sec; weekly: 5 min; monthly: 10 min
Onboard maintenance records Time from communication of problem to engineer on site	yes	yes
Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem	yes/no	yes/no —
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	MAPSS cell-by-cell analysis; retic. with reportable IRF (immature retic.	MAPSS cell-by-cell analysis provides enhanced diff.; focused flow
	fraction); up to 60 different animal types may be configured for analysis; *please see the corresponding operator's manual for product labeling, including warnings, limitations, and precautions	2-D optical RBC and Plt analysis provides better separation between microcytic RBCs and large Plts; uses only three reagents; 3-D MCV; *please see the corresponding operator's manual for product labeling, including warnings, limitations, and precautions

22 / CAP TODAY		December 2009
	Hematology analyzers	
Part 4 of 13	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-3183 www.beckmancoulter.com	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-3183 www.beckmancoulter.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2008 No. units installed in U.S./outside U.S./list price	UniCel DxH 800 2008/2008/2 30/20/\$219,000 or \$229,000 with floor stand	LH 1500 Hematology Automation Series 2002/2003/15 >65/25/varies
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso):	standard menu (left) plus: RDW-CV, RDW-SD, MPV, retic#, retic%, IRF, MRV, NRBC# and %, body fluids-total nucleated count, and RBC count for synovial, serous, and CSF fluids.	standard menu (left) plus: RDW, MPV, retic %&#, IRF, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids</td></tr><tr><td>• Laboratory • Flags</td><td>definitive, suspect and system messages, user-definable extended decision rules, ISLH consensus rules, user-definable differential sensitivity</td><td>user-definable age-, gender-, and/or location-based ref. intervals; action and critical limits; user-def. RBC morph.; user-selectable sensitivity for diff., abnormal population suspect messages</td></tr><tr><td>FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only</td><td>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</td><td>——————————————————————————————————————</td></tr><tr><td>Tests unique to analyzer</td><td>width (RDWR-CV and RDWR-SD), red cell size factor (RSF), cell population data research parameters</td><td>IVD: NRBC, body fluids; RUO: MSCV, WBC RPD</td></tr><tr><td>Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet</td><td>flow cytometric digital analysis using volume, conductivity, and five angles of light scatter, digital signal processing, advanced algorithm applications, high-definition cellular resoluton, DataFusion $0-400/0-8.5$ $0-25.5/0-3,000$ $50-150$ $\le 3.0\%/\le 1.5\%$ $\le 1.5\%/$ $\le 3.5\%/$</td><td>Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate and AccuFlex technologies 0-400/0-8.0 0-25/0-3,000 50-200 (MCV) <1.7%/<0.8% <0.8%/<3.3%</td></tr><tr><td>• MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • RBC</td><td>≤1.0% ≤1.0% NE = ±2.0; LY, MO = ±3.0; E0,BA = ±1.0 (or 10%, whichever is greater), — precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant red cells, giant platelets, platelet clumps, unlysed particles > 35 fL in size very high WBC count, high concentration of very large platelets, autoagglutination</td><td><0.8% (MCV) lymph% = $\pm 3.0\%$, —; neut% = $\pm 3.0\%$, —; mono% = $\pm 2.0\%$, —; eos% = $\pm 1.0\%$, —; baso% = $\pm 1.0\%$, — unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins</td></tr><tr><td>MCV or Hct Platelet Hemoglobin Interfering substances: differential</td><td>very high WBC count, high concentration of very large platelets, autoagglutination platelet clumps, white cell fragments, very small red cells, red cell fragments severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing elevated triglycerides, precipitated elevated proteins</td><td>very high WBC, high conc. large Plt, autoagglutinins very small RBCs & WBC frags. may interfere very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing</td></tr><tr><td>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price</td><td>yes >100 per hour/>100 per hour two times per year or per regulatory requirements CBC/RBC, WBC, Hgb, MCV, PLT, MPV per regulatory requirements/daily 165 µL/165 µL/300—400 µL yes (variety of sizes) no yes yes</td><td>yes 105 per analyzer on automation system/105 per analyzer on automation sys. as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hb, MCV, PIt, 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 >850 (U.S.)/\$110,000</td></tr><tr><td>Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: color with threshold Choice of desired specimen and/or result info. displayed</td><td>yes yes 40,000 standalone; 120,000 in workcell 40,000 standalone; 120,000 in workcell 40,000 yes yes yes yes yes yes yes yes yes yes</td><td>yes yes 20,000 samples per instrument 20,000 samples per instrument yes yes yes yes yes yes yes yes yes yes</td></tr><tr><td>LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features</td><td>ASTM 1394 and 1381 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) yes phone or Web support yes, BCI enhanced QC, data archiving, data collation from multiple instruments, user-</td><td>RS-232 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast no contact technical support yes, DL2000, Command Central support of Contact archivers data callection from multiple instruments.</td></tr><tr><td>Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A</td><td>definable decision rules, ISLH rules, delta check included with DxH; Remisol Advance also available Beckman Coulter Codabar, codes 39 and 128, interl. 2 of 5, NW7 yes</td><td>enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results and graphics Beckman Coulter Codabar, codes 39 and 128, interl. 2 of 5, NW7 yes</td></tr><tr><td>Time required for maintenance by lab personnel</td><td>daily: 2 min; weekly: as needed; monthly: as needed</td><td>daily: automation system= 5 min, analyzer=0 min; weekly: automation=10 min, analyzer=0 min; monthly: automation=15 min, analyzer=2 min</td></tr><tr><td>Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem</td><td>yes varies yes/no yes</td><td>yes/no yes</td></tr><tr><td>Acquisition program based on cost-per-reportable result</td><td>yes</td><td>yes</td></tr><tr><td>Distinguishing features</td><td>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 retic analysis; digital signal processing, DataFusion; future scalability options include DxH workcells with trackless connectability; intelligent workload distribution; configurable with up to four analyzers; integrated slidemaker/slidestainer; consolidated database</td><td>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 type of test; multiple configurations available; RUO: WBC research population data</td></tr></tbody></table>

24 / CAR TODAY		December 2000
24 / CAP TODAY	Hematology analyzers	December 2009
Part 5 of 13	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-3183 www.beckmancoulter.com	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-3183 www.beckmancoulter.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 20 No. units installed in U.S./outside U.S./list price	LH 780/LH 785 08 2006/2007/160 >460/>475/LH 780: \$214,500; LH 785: \$389,500	Coulter LH 750 2001/2001/250 (U.S.) >2,400/>2,300/\$195,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, M MCH, MCHC, Plt, %&# neut, mono, lymph, eos, ba • Laboratory		standard menu (left) plus: RDW, MPV, retic #&%, IRF, MPV, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial, and serous fluids</td></tr><tr><th>Flags FDA-cleared tests but not clinically released</th><td>user-definable age-, gender-, and/or location-based ref. intervals; action and critical limits, user-def. RBC morph.; user-def. sensitivity for diff. abnormal populations, suspect and definitive messages —</td><td>user-definable age-, gender-, and/or location-based ref. intervals; action and critical limits; user-def. RBC morph.; gradient msgs. $(=+,++,++++)$; user-selectable sensitivity for diff. abnormal population suspect messages —</td></tr><tr><th>Tests not available but submitted for clearance Tests in development For research use only</th><td>— — RSF, MAF, MSCV, HLR %&#, RDWR-CV, RDWR-SD, PDW, PCT, WBC research</td><td>— — MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD)</td></tr><tr><th>Tests unique to analyzer</th><th>population data (RPD) IVD: NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD</th><th>IVD: NRBC, body fluids; RUO: MSCV, WBC RPD</th></tr><tr><th>Differential method(s) used Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet • Hemoglobin</th><td>Coulter's 3-D VCS biophysical flow cytometry with Intellikinetics, AccuGate & AccuFlex technologies 0-400/0-8.0 0-25/0-3,000 50-200 (MCV) <1.7%/<0.8% <0.8%/<3.3% <0.8% (MCV) lymph% = ±3.0%, —; neut% = ±3.0%, —; mono% = ±2.0%, —; eos% = ±1.0%, —; baso% = ±1.0%, — unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins very high WBC, high conc. large Plt, autoagglutinins (MCV) very small RBCs & WBC frags.</td><td>Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & AccuFlex technologies 0–400/0–8.0 0–25/0–3,000 50–200 (McV) <1.7%/<0.8% <0.8%/<3.3% <0.8% (McV) lymph% = ±3.0%, —; neut% = ±3.0%, —; mono% = ±2.0%, —; eos% = ±1.0%, —; baso% = ±1.0%, — unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins very small RBCs & WBC frags. may interfere very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs</td></tr><tr><th>Interfering substances: differential Age- and sex-specific reference ranges</th><th>high triglycerides may affect lysing</th><th>high triglycerides may affect lysing</th></tr><tr><th>Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems slide prep If automatic slidemaker available, No. installed/list price</th><td>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 for yes >50/\$110,000</td><td>yes 105/105 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 (multiple sizes and styles) no yes yes, both >900 (U.S.)/\$110,000</td></tr><tr><th>Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens Stored in conjunction with CBC data Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmis Performs delta checks Tags and holds results for followup, confirm. testing, or reruly 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 info. displayed</th><td>yes</td><td>yes yes 20,000 samples 20,000 samples 20,000 samples yes yes yes yes yes yes yes yes yes y</td></tr><tr><th>LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2</th><td>Codabar, codes 39 and 128, interl. 2 of 5 A yes</td><td>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 Beckman Coulter Codabar, codes 39 and 128, interl. 2 of 5, NW7 yes</td></tr><tr><th>Time required for maintenance by lab personnel</th><td>daily: 0 min: weekly: 0 min: monthly: 2 min</td><td>daily: 0 min: weekly: 0 min: monthly: 2 min</td></tr></tbody></table>

daily: 0 min; weekly: 0 min; monthly: 2 min

Time required for maintenance by lab personnel yes

Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem Acquisition program based on cost-per-reportable result

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 **Distinguishing features**

yes/no

yes

yes

extensive decision support; enumeration of NRBCs with every diff.; random access; automation ready; extended linearity for WBC and Plts; RUO: WBC RPD $\,$

daily: 0 min; weekly: 0 min; monthly: 2 min

yes

yes

yes

yes/no

Hematology analyzers		
Part 6 of 13	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-3183 www.beckmancoulter.com	Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-3183 www.beckmancoulter.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2008 No. units installed in U.S./outside U.S./list price	Coulter LH 500 2003/2003/200 (U.S. only) >1,300/>1,700/\$145,000	Coulter HmX 1999 HmX AL >1,140/>2,200/\$135,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso): • Laboratory • Flags	standard menu (left) plus: retic #, retic %, MRV, IRF, RDW, MPV — user-definable age-, gender- and/or location-based ref. intervals, action and	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV — comprehensive high/low, definitive and suspect messages
FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only	critical limits; user-def. RBC morph.; gradient msgs. none none none PCT, PDW	none none none PCT, PDW
Tests unique to analyzer	none	none
Differential method(s) used Linearity: • WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) • Hemoglobin (g/dL)/platelet (10 ⁹ /L) • MCV (fL) or Hct (%)	Coulter's 3-D biophysical flow cytometry with AccuGate 500, Reaction Manager technologies 0-200/0-8.0 0-25/0-2,000 50-150 (MCV)	Coulter's 3-D VCS technology 0-99.9/0-7.0 0-25/0-999 50-150 (MCV)
Precision:	$2.5\%/\le 2.0\%$ $1.5\%/\le 5.0\%$ 2% (MCV) lymph= $\pm 1.5\%$ mean diff., —; mono= $\pm 1.5\%$ mean diff., —; neut= $\pm 2.0\%$ mean diff., —; eos= $\pm 0.5\%$ mean diff., —	<2.5%/<2.0% <1.5%/<5.0% <2.0% (MCV) lymph%= ±3.0%, —; mono%= ±2.0%, —; neut%= ±3.0%, —; eos%= ±1.0%, —; baso%= ±1.0%, —
Interfering substances: • WBC • RBC	lyse-resistant, nucleated RBCs, frag. WBCs, agglut. WBCs, unlysed particles >35 fL, very large or agg. Plts, fibrin, cell frag., or other debris very high WBC count, many very large Plts, agglut. RBCs, RBCs <36 fL, fibrin, cell fragments, or other debris	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt very high WBC, high conc. of very large Plt, autoagglutinins
MCV or Hct Platelet	MCV: very high WBC count, high concentration of very large Plts, agglut. RBCs, RBC fragments <36 fL, rigid RBCs very small red cells near the upper threshold, cell fragments, clumped Plts, Plt frag. or cellular debris near the lower Plt threshold, giant Plts, Plt clumps, red &	MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins very small RBCs & WBC frags. may cause no fit
Hemoglobin Interfering substances: differential	white cell frag., electronic noise, very small red cells very high WBC count, severe lipemia, heparin, lyse-resistant RBCs, turbidity such as elevated triglycerides factors that affect WBC count above or high triglycerides that affect lysing, hypogran. granulocytes, agranul. granulocytes, lyse-resist. red cells, very small	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing
	or multi-population lymphocytes, elevat. trigly., precipitated elev. proteins	
Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price	yes 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 μ L/185 μ L/tube dependent yes (10.25 \times 75 mm or less; 13 \times 75 mm or less) no yes no	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 (multiple sizes and styles) no yes no
Archives patient data for later comparison	yes	yes
Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed	yes 20,000 samples 20,000 samples 20,000 samples yes yes yes yes yes yes yes yes yes y	yes 5,000 samples 5,000 samples 5,000 samples yes yes yes yes yes no yes user or vendor yes, through a selective batch process 4 colors/cell types colors without thresholds no
LIS interface formats supported Information transferred on LIS interface	RS-232, proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	RS-232, proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features	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 & graphics, centralized management of instruments	no technical support yes, DL2000 enhanced QC, data archiving, common database, delta checking, patient results and graphics
Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A	Codabar, codes 39 and 128, ASTM, interl. 2 of 5, NW7 yes	Codabar, codes 39 and 128, interl. 2 of 5, NW7
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 Mftr. can perform diagnostics via modem	yes — yes/no yes	no — yes/no no
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	extensive decision support, extended linearity for WBC & Plt, low review rate, small footprint, superior reliability, ProService, electronic IQAP	VCS technology; low review rate; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single-sample models

26 / CAP TODAY		December 2009
	Hematology analyzers	
Part 7 of 13	Beckman Coulter Inc. Kelly Colwell KMColwell@beckman.com 250 So. Kraemer Blvd Brea, CA 92821 714-961-4110	Horiba Medical Jim Knowles jknowles@horiba.com 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2008 No. units installed in U.S./outside U.S./list price	www.beckmancoulter.com 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	www.horiba.com Pentra 60C+ Hematology Analyzer 2000/2000/85 510/1,038/\$45,476
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	standard menu (left) plus: RDW, MPV atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW complete operator selectable flagging none none	standard menu (left) plus: RDW, MPV atyp. lymph, atyp. lymph %, LIC, LIC % operator selectable flagging none none
Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer	none PCT, PDW, IMM, ATL	none PCT PDW none
Differential method(s) used Linearity: • WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) • Hemoglobin (g/dL)/platelet (10 ⁹ /L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation	AcV technology combining cytochemistry, focused flow impedance, and light absorbance prinicples of measurement 0.4–91.3/0.3–8.0*; AL: 0.4–120.0/0.3–8.0 0–22/10–1,000*; AL: 1.3–24.0/10.0–1,000 1.8–63.8 (Hct)* <2%/<2% <1%/<5% <1.0% (Hct); AL: <2.0% (Hct) not available in NCCLS H-20A format	DHSS technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement $0-120/0-8$ $0.7-24/0-1,900$ $0.7-67$ (Hct) $<2\%/2\%$ $<1\%/5\%$ $<2\%$ (Hct) 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	NRBCs, Plt clumps, large Plts, lyse-resistant RBCs cold agglutinins, Plt clumps, WBC overlinearity Hct: lipemic samples, high WBC, cold aggluts	NRBCs, Plt clumps, lyse-resistant RBCs cold agglutinins Hct: extreme leukocytosis
Platelet Hemoglobin Interfering substances: differential	RBC and WBC fragments elevated WBC, lipemia	microcytes, Plt clumps extreme lipemia/leukocytosis
Age- and sex-specific reference ranges	lyse-resistant RBCs, NRBCs, lipemia yes	NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia yes
Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib.	60/60; 80/80 not specified by time	6060 6 months
Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed	open or closed/RBC, WBC, Hb, Hct, Plt not specified/none	closed-open/WBC, RBC, Hb, Hct, Pit, MPV per CLIA standards/none
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC-diff./53 µL for CBC-diff./varies by tube size yes (multiple sizes) no yes	30 µL for CBC & 53 µL for CBC + diff./30 µL for CBC & 53 µL for CBC + diff./— yes (multiple sizes) yes yes yes
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	CBC-diff./varies by tube size yes (multiple sizes) no yes no —	yes (multiple sizes) yes yes yes yes —
Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep	CBC-diff./varies by tube size yes (multiple sizes) no yes	yes (multiple sizes) yes yes
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 Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system	CBC-diff./varies by tube size yes (multiple sizes) no yes no — yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y	yes (multiple sizes) yes yes yes yes — yes yes, with back-up drive unlimited with back-up drive 10,000, unlimited with back-up drive yes yes yes yes yes yes yes yes yes ye
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 Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features	CBC-diff./varies by tube size yes (multiple sizes) no yes no yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y	yes (multiple sizes) yes yes yes yes yes, with back-up drive unlimited with back-up drive 10,000, unlimited with back-up drive 10,000, unlimited with back-up drive yes yes yes yes yes yes yes yes yes ye
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 Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube	CBC-diff./varies by tube size yes (multiple sizes) no yes no 10,000 samples 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y	yes (multiple sizes) yes

quant. five-part WBC diff.; aspirates only 30 μL of sample; requires small space footprint and runs quietly; AL has auto repeat based on decision rules

reliable five-part WBC diff. technology—MTBF more than 200 days; small footprint; small sample size of 53 μL

* linearity stated for AculletT 5diff CP

Distinguishing features

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Part 8 of 13	Horiba Medical Jim Knowles jknowles@horiba.com 34 Bunsen Irvine, CA 92618	Horiba Medical Jim Knowles jknowles@horiba.com 34 Bunsen Irvine, CA 92618
	888-903-5001 ext. 553 www.horiba.com	888-903-5001 ext. 553 www.horiba.com
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2008 No. units installed in U.S./outside U.S./list price	Pentra XL 80 2004/2003/31 186/510/\$73,826	Pentra DX120 2005/2004/6 36/648/\$199,500
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso): • Laboratory	standard menu (left) plus: automatic dilution of overrange results (WBC \times 3, RBC/hgb/Plt \times 2), RDW, MPV atyp. lymph, atyp. lymph%, LIC, LIC%	standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%, RETH%, IMR%, MRU, MFI%, CRC%</td></tr><tr><td>• Flags</td><td>operator selectable flagging</td><td></td></tr><tr><td>FDA-cleared tests but not clinically released Tests not available but submitted for clearance</td><td>none none</td><td>none none</td></tr><tr><td>Tests in development For research use only</td><td>none PCT PDW</td><td>none PCT PDW, IMG, IML, IMM</td></tr><tr><td>Tests unique to analyzer</td><td>automatic dilution protocol</td><td>_</td></tr><tr><td>Differential method(s) used</td><td>DHSS technology combining cytochemistry, focused flow impedance and light</td><td>cytochemistry (chlorazol black E) and absorbance</td></tr><tr><td>Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L)</td><td>absorbance 0–120/0–8</td><td>0-150/0.5-8.1</td></tr><tr><td> Hemoglobin (g/dL)/platelet (10⁹/L) MCV (fL) or Hct (%) </td><td>0-24/0-1,900 (>2 g/dL Hb) 0-67 (Hct)/0-2,800 (<2 g/dL Hb)</td><td>2–25/0–2,000 0–80 (Hct)</td></tr><tr><td>Precision: • WBC count/RBC count • Hemoglobin/platelet</td><td><2%/<2% <1%/<5%</td><td><2%/<2% <1%/<5%</td></tr><tr><td>MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation</td><td><2% (Hct) neut% r=0.99, —; lymph% r=0.98, —; mono% r=0.96, —; eos% r=0.89, —; baso% r=0.54, —</td><td><2% (Hct) neut% r=0.99, —; lymph% r=0.98, —; mono% r=0.92, —; eos% r=0.97, —; baso% r=0.71, —</td></tr><tr><td>Interfering substances: • WBC</td><td>NRBCs, Pit clumps, lyse-resistant RBCs</td><td>NRBCs, Plt clumps, lyse-resistant RBCs</td></tr><tr><td>• RBC</td><td>cold agglutinins</td><td>cold agglutinins</td></tr><tr><td>MCV or Hct</td><td>Hct: extreme leukocytosis</td><td>Hct: extreme leukocytosis</td></tr><tr><td>• Platelet</td><td>microcytes, Plt clumps</td><td>microcytes, Plt clumps</td></tr><tr><td>• Hemoglobin</td><td>extreme lipemia, leukocytosis</td><td>extreme lipemia, leukocytosis</td></tr><tr><td>Interfering substances: differential</td><td>NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</td><td>NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</td></tr><tr><td>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib.</td><td>yes 80/80 6 months</td><td>yes 120/120 6 months</td></tr><tr><td>Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed</td><td>open, closed/WBC, RBC, Hb, Hct, Plt, MPV per CLIA standards/none 30 µL for CBC/53 µL for CBC + diff./0.5 mL</td><td>open, closed/WBC, RBC, Hb, Hct, Plt, MPV per CLIA standards/none 130 µL/200 µL/1 mL</td></tr><tr><td>Tube sampling supported</td><td>yes (autoloader 13 \times 75 mm; closed tube 16 sizes + micro)</td><td>yes</td></tr><tr><td>Veterinary capability Microsample capability</td><td>yes yes</td><td>yes yes, open mode</td></tr><tr><td>Prepares microscopic slides automatically or flags problems for slide prep</td><td>yes —/—</td><td>yes —/—</td></tr><tr><td>If automatic slidemaker available, No. installed/list price Archives patient data for later comparison</td><td>yes</td><td>yes</td></tr><tr><td>Patient-specific archiving Max. archived data accessible when system online</td><td>yes, with MultiLink Data Manager MultiLink Data Manager; 10,000 instrument only</td><td>yes yes unlimited Data Manager; 10,000 instrument only</td></tr><tr><td>Memory capacity—numeric results–No. specimens</td><td>MultiLink Data Manager; 10,000 instrument only</td><td>unlimited Data Manager</td></tr><tr><td>Memory capacity—histo/cytograms–No. specimens • Stored in conjunction with CBC data</td><td>MultiLink Data Manager yes</td><td>unlimited Data Manager yes</td></tr><tr><td>Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted</td><td>yes yes</td><td>yes yes</td></tr><tr><td>Saved data can be sorted for reprocessing or report transmission Performs delta checks</td><td>yes yes</td><td>yes yes</td></tr><tr><td>Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by</td><td>yes user</td><td>yes user</td></tr><tr><td>Some results can be transmitted to LIS while others held Scattergram display: cell-specific color</td><td>yes yes</td><td>— yes</td></tr><tr><td>Histogram display: color with threshold Choice of desired specimen and/or result info. displayed</td><td>yes —</td><td>yes yes</td></tr><tr><td>LIS interface formats supported Information transferred on LIS interface</td><td>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</td><td>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</td></tr><tr><td>LOINC codes transmitted with results How labs get LOINC codes for reagent kits</td><td>— — — — — — — — — — — — — — — — — — —</td><td>- Dioducast</td></tr><tr><td>Optional data mgmt. or collation system • Software features</td><td>yes (MultiLink) enhanced QC, data archiving, data collation from multiple instruments</td><td>yes (MultiLink) enhanced QC, data archiving, data collation from multiple instruments</td></tr><tr><td>Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A</td><td>yes Codabar, codes 39 and 128, ASTM, interl. 2 of 5 yes</td><td>yes Codabar, codes 39 and 128, ASTM, interl. 2 of 5 yes</td></tr><tr><td>Time required for maintenance by lab personnel</td><td>weekly: 15 min</td><td>weekly: 15 min</td></tr><tr><td>Onboard maintenance records</td><td>yes</td><td>yes</td></tr><tr><td>Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem</td><td>24 hrs no/yes</td><td>no/yes</td></tr><tr><td>Mftr. can perform diagnostics via modem</td><td>yes</td><td>yes</td></tr><tr><td>Acquisition program based on cost-per-reportable result</td><td>yes</td><td>high throughout call counter with integrated reticularity methodology and</td></tr><tr><td>Distinguishing features</td><td>compact five-part differential instrument with autoloader and autodilution capability, autorerun feature, autovalidation</td><td>high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, autovalidation</td></tr></tbody></table>

Hematology analyzers		
Part 9 of 13	Siemens Healthcare Diagnostics Rita White rita.f.white@siemens.com 500 GBC Drive Newark, DE 19702 888-899-2896 http://www.usa.siemens.com/diagnostics	Siemens Healthcare Diagnostics Rita White rita.f.white@siemens.com 500 GBC Drive Newark, DE 19702 888-899-2896 http://www.usa.siemens.com/diagnostics
Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2008 No. units installed in U.S./outside U.S./list price	Advia 120 Hematology System 1998/1998/— >750/3,500/\$169,000-\$189,000	Advia 2120 Hematology System 2004/2004/— >200/>900/\$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, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellular Hgb %: hypo, hyper, macro, micro; calc. Hb, MPXI; %: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost count left shift, atyp. lymph, blasts, immature grans, myeloperox. deficiency, aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC frag., RBC ghost, large Plt, Plt clumps none none IRF, MPC, MPM CSF, eos CHCM, HDW, CHr, CHCMr, MPC, MPM; CSF: WBC RBC, MN, PMN, neut, lymph, mono</td><td>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 left shift, atyp. lymph, blasts, immature grans, myeloperox. deficiency, aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC frag., RBC ghost, large Plt, Plt clumps none none MPC, MPM IRF, CSF, eos CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono</td></tr><tr><td>Differential method(s) used Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (ft.) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet • Hemoglobin Interfering substances: differential</td><td>perox-peroxidase cytochem. staining with light scatter and absorption; baso-cytochem. stripping with 2-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%/1.2% 0.93%/2.93% 0.78% (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 bili., interfere with cyanmethb. only, none with direct cellular Hb (CHCM) incomplete lysis of RBCs, complete myeloperox. deficiency</td><td>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%/1.2% 0.93%/2.93% 0.78% (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 none none extreme lipemia, high WBC, extreme high bili. interference w/ colorimetric Hb only, none with cellular Hb incomplete RBC lysis, complete myeloperox. deficiency</td></tr><tr><td>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price</td><td>yes 120/120 6 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</td><td>yes 120/120 6 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</td></tr><tr><td>Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed</td><td>yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y</td><td>yes no 10,000 10,000 10,000 yes yes yes yes yes yes yes yes yes yes</td></tr><tr><td>LIS interface formats supported Information transferred on LIS interface</td><td>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</td><td>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)</td></tr><tr><td>LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube</td><td>no online documentation yes (CentraLink) enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated diff. pad, remote diagnostics, remote workstations LabCell (Siemens) Codabar, codes 39 and 128, ASTM, interl. 2 of 5</td><td>no online documentation yes (CentraLink) enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated diff. pad, remote diagnostics, remote workstations LabCell (Siemens) Codabar, codes 39 and 128, interl. 2 of 5</td></tr><tr><td>Accommodates bar-code placement per CLSI standard Auto2A Time required for maintenance by lab personnel</td><td>daily: 10 min; weekly: 15 min; monthly: 15 min</td><td>daily: 0 min; weekly: 15 min; monthly: 15 min</td></tr><tr><td>Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mftr. can perform diagnostics via modem</td><td>yes territory dependent yes/no yes</td><td>yes territory dependent yes/no yes</td></tr><tr><td>Acquisition program based on cost-per-reportable result</td><td>yes</td><td>yes</td></tr><tr><td>Distinguishing features</td><td>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</td><td>unique laser technology provides direct 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</td></tr></tbody></table>	

	Hematology analyzers	
Part 10 of 13	Siemens Healthcare Diagnostics Rita White rita.f.white@siemens.com 500 GBC Drive Newark, DE 19702 888-899-2896 http://www.usa.siemens.com/diagnostics	Sysmex America Inc. Tammy Kutz kutzt@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 2008 No. units installed in U.S./outside U.S./list price	Advia 2120i 2008/2008/— —/—/\$225,000	XE-5000 2009/2008/115 155/800/\$265,122
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso): • Laboratory • Flags	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 left shift, atyp. lymph, blasts, immature grans, myeloperox. deficiency, aniso,</td><td>standard menu (left) plus: NRBC %&#, Retic %&#, RDW-SD, RDW-CV, IRF, Plt-0, HPC#, MPV, IG%, IG#, RET-He, IPF none Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast, left shift,</td></tr><tr><th>FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only</th><th>micro, macro, Hgb variation, hypo, hyper, NRBC, RBC frag, RBC ghost, large Plt, Plt clumps none none MPC, MPM IRF, CSF eos</th><th>atyp. lymph., ABN lymph./blast, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity none none none none</th></tr><tr><th>Tests unique to analyzer</th><th>CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono</th><th>reticulocyte hemoglobin, immature platelet fraction, hematopoietic progenitor cell, immature reticulocyte fraction, reportable immature granulocyte #&%</th></tr><tr><th>Differential method(s) used Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet • Hemoglobin Interfering substances: differential</th><td>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%/1.2% 0.93%/2.93% 0.78% (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 bili.—interference w/colorimetric Hgb only, none with cellular Hgb incomplete RBC lysis, complete myeloperoxidase deficiency</td><td>fluorescent flow cytometry, RF/DC detection method 0-440/0-8 0-25/0-5,000 0-75 (Hct) <3%/<1.5% <1.0%/<4.0% <1.5% (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 agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs cold agglut, severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis Hct: cold agglutinins, leukocytosis, ABN red cell fragility, spherocytosis pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts lipemia, ABN proteins, leukocytosis (>100,000/μL) lyse-resistant RBCs</td></tr><tr><th>Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If automatic slidemaker available, No. installed/list price</th><th>yes 120/120 6 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</th><th>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 μL/200 μL/1 mL yes no yes yes (with Alpha or HST upgrade) >1,200/price depends on configuration</th></tr><tr><th>Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed</th><td>yes no 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y</td><td>yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y</td></tr><tr><th>LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A</th><th>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 diff. pad, remote diagnostics, remote workstations LabCell (Siemens) Codabar, codes 39 and 128, ASTM, interleaved 2 of 5 yes</th><th>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 yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, rules setting Roche Diagnostics, and Labotix, A & T, Thermo, IDS Codabar, codes 39 and 128, ASTM, interleaved 2 of 5, ITF, NW7, EAN 8 and 13</th></tr><tr><th>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 Mftr. can perform diagnostics via modem</th><th>daily: 10 min; weekly: 15 min; monthly: 15 min yes territory dependent yes/no yes</th><th>daily: <3 min yes <24 hours yes/no yes, also via Internet</th></tr><tr><th>Acquisition program based on cost-per-reportable result</th><th>yes</th><th>yes</th></tr><tr><th>Distinguishing features</th><th>laser technology provides direct cellular Hgb for RBCs and retics; 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</th><th>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%; hematopoietic progenitor cell testing; immature granulocyte enumeration; immature platelet fraction; reticulocyte hemoglobin equivalent; standardized reagents, controls and operations with other Sysmex X series analyzers</th></tr></tbody></table>	

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Pit clumps, RBO agglut, furbidity, MBC ABM scattergram, RBC ABM distribution, WBC ABM scattergram, NBC ABM distribution, WBC ABM scattergram, NBC ABM distribution, WBC ABM scattergram, NBC ABM distribution, WBC ABM scattergram non none none none none none none none
ABM distrib. RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph.
FBA-cleared tests but not clinically released none
Tests unique to analyzer P-CR, PCT, PDW P-LCR, PCT, PDW Differential method(s) used Ituorescent flow cytometry Ituarity: *WBC count (10 ⁹ /L)/RBC count (10 ¹² /L)
For research use only
Differential method(s) used Linearity: * WBC count (10 ¹⁰ /L)/ABC count (10 ¹² /L)
Linearity: *WBC count (10 ¹⁹ /L)/RBC count (10 ¹⁹ /L)
Hemoglobin (grld.)/platelet (10°/L)
Hemoglobin (grld.)/platelet (10°/L)
Precision: • WBC count/RBC count • Hemoglobin/patetet • MCV or Hct • MCV or Hct • MBC • MB
* MCV or Hot Accuracy of automated diff. compared with manual diff. (per CLSH +20A), regression equation y=0.75, 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=0.95, y=0.82x+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=0.95, y=0.82x+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=0.92, y=0.92x+0.922 cold agult., baso%
Accuracy of automated diff. compared with manual diff. (per CLSI H-2OA), regression equation y=0.77x+1.88; eos% r=0.92, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.73, y=0.77x+1.88; eos% r=0.92, y=0.97x+1.81; eos% r=0.92, y=0.97x+1.81; eos% r=0.92, y=0.97x+1.81; eos% r=0.92, y=0.97x+1.81; eos% r=0.92, y=0.97x+0.29; basow f=0.92, y=0.93x+0.092; basow f=0.92, y=0.9
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• RBC • MCV or Hct • MCV or Hct • Platelet • Hemoglobin Interfering substances: differential Interfering substances: differential
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MCV or Hct Platelet Hct: cold agglutinins, leukocytosis, ABN red cell fragility, spherocytosis pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts Hemoglobin lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis, leukocytosis, pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN p
• Hemoglobin lipemia, ABN proteins, leukocytosis (>100,000/μL) lipemia, ABN proteins, leukocytosis (>100,000/μL) Interfering substances: differential lyse-resistant RBCs lyse-resistant RBCs Age- and sex-specific reference ranges yes yes Max. CBCs per hr/max. CBCs & diffs. per hr 150/150 150/150 Recommended average frequency of calib. once per year by FSR once per year by FSR • Modes calibrated/parameters calibrated open, closed, capillary/WBC, RBC, Hb, Hct, Plt open, closed, capillary/WBC, RBC, Hb, Hct, Plt Frequency of blood/latex controls per requirements/none per CLIA requirements/none Min. specimen vol. open/closed/sample dead vol. closed 130 μL/200 μL/1 mL 130 μL/200 μL/1 mL Tube sampling supported yes yes Veterinary capability no no Microsample capability yes yes Prepares microscopic slides automatically or flags problems for yes with Alpha or HST upgrade yes, with Alpha or HST upgrade
Interfering substances: differential lyse-resistant RBCs lyse-resistant RBCs Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr 150/150 Recommended average frequency of calib. • Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Nes Ves Ves Ves Ves Ves Ves Ves Ves Verpares microscopic slides automatically or flags problems for Verpares microscopic slides automatically or flags problems for Pes Yes Yes Yes Yes Yes Yes Yes Yes Yes
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Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. • Modes calibrated/parameters calibrated • Modes calibrated/parameters calibrated • Modes calibrated/parameters calibrated • Modes calibrated/parameters calibrated • per requirements/none Min. specimen vol. open/closed/sample dead vol. closed 130 μL/200 μL/1 mL Tube sampling supported yes Veterinary capability no Microsample capability Prepares microscopic slides automatically or flags problems for 150/150 150/150 once per year by FSR open, closed, capillary/WBC, RBC, Hb, Hct, Plt per CLIA requirements/none 130 μL/200 μL/1 mL 130 μL/200 μL/1 mL 130 μL/200 μL/1 mL yes yes yes yes yes yes yes ye
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Veterinary capability no no no Microsample capability yes yes Prepares microscopic slides automatically or flags problems for yes with Alpha or HST upgrade yes, with Alpha or HST upgrade
Prepares microscopic slides automatically or flags problems for yes with Alpha or HST upgrade yes, with Alpha or HST upgrade
Slide Dred
If automatic slidemaker available, No. installed/list price >1,000/price depends on configuration >1,000/price depends on configuration
Archives patient data for later comparison yes yes
Patient-specific archiving yes yes Max. archived data accessible when system online 10,000 samples 10,000 samples
Memory capacity—numeric results–No. specimens 10,000 samples 10,000 samples
Memory capacity—histo/cytograms=No. specimens 10,000 samples 10,000 samples • Stored in conjunction with CBC data yes yes
Histo/cytogram images & CBC data printed as 1 report yes Saved results can be recalled and retransmitted yes yes
Saved data can be sorted for reprocessing or report transmission yes yes Performs delta checks yes yes
Tags and holds results for followup, confirm. testing, or rerun yes yes
Parameters for flags for holding samples are defined by user or vendor user or vendor Some results can be transmitted to LIS while others held yes yes
Scattergram display: cell-specific color yes yes Histogram display: color with threshold yes yes
Choice of desired specimen and/or result info. displayed yes yes
LIS interface formats supported RS-232C/TCP IP RS-232C/TCP IP RS-232C/TCP IP RUMPATION transferred on LIS interface RUMPATION transferred on LIS interface RUMPATION transferred on LIS interface RS-232C/TCP IP
Information transferred on LIS interface numeric and flag results, histograms and scatterplots, patient demographics, orders numeric and flag results, histograms and scatterplots, patient demographics, orders
LOINC codes transmitted with results yes yes How labs get LOINC codes for reagent kits contact vendor contact vendor
Optional data mgmt. or collation system yes, Sysmex WAM (Work Area Manager) • Software features yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments, enhanced QC, data archiving, data collation from multiple instruments.
multiple sites sites
Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube October 1. Codabar, codes 39 and 128, interl. 2 of 5, ITF, NW7, EAN 8 and 13 October 2. Codabar, codes 39 and 128, ASTM, interl. 2 of 5, ITF, NW7, EAN 8 and 13
Accommodates bar-code placement per CLSI standard Auto2A yes yes
Time required for maintenance by lab personnel daily: <3 min. daily: <3 min.
Onboard maintenance records yes yes
Time from communication of problem to engineer on site <24 hours <24 hours Onboard diagnostics/limited to software problems yes/no yes/no
Mftr. can perform diagnostics via modem yes, also via Internet yes, also via Internet
Acquisition program based on cost-per-reportable result yes yes
Distinguishing features throughput of 150 CBCs per hour; random access; discrete testing; online 150 CBC/hr; platelet linearity—5 million, hematocrit extended to 75 percent;
QC; remote diagnostics, body fluid analysis; platelet linearity to 5 million, standardized technology, reagents, controls and operations; ISBT compliant; new FDA-cleared application for blood component products in specified
granulocyte enumeration; immature platelet fraction; reticulocyte hemoglobin anticoagulants
equivalent; standardized reagents, controls and operations with other Sysmex

34 / CAP TODAY	Homotology analyzore	December 2009
	Hematology analyzers	
Part 12 of 13	Sysmex America Inc. Tammy Kutz kutzt@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Tammy Kutz kutzt@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 2008 No. units installed in U.S./outside U.S./list price	Sysmex XE-Alpha N/HST-N 2000/—/50 >600/1,100/\$360,000-\$1,000,000	Sysmex XT-2000i 2002/2001/160 4,900 worldwide/\$145,000
Test menu: • Chartable (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso):	standard menu (left) plus: NRBC%&#, Retic%&#, RDW-SD, RDW-CV, IRF, PLT-0, HPC#, MPV, IG%, IG#, RET-He, IPF</td><td>standard menu (left) plus: retic %&#, IRF, Plt-0, MPV, RDW-SD, RDW-CV, reticulocyte hemoglobin, immature granulocytes %&#</td></tr><tr><td>• Laboratory • Flags</td><td>none user defined, all inclusive</td><td>none Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity, NRBC, body fluids</td></tr><tr><td>FDA-cleared tests but not clinically released Tests not available but submitted for clearance</td><td>none none</td><td></td></tr><tr><td>Tests in development For research use only</td><td>P-LCR, PCT, PDW</td><td>_</td></tr><tr><td>Tests unique to analyzer</td><td>NRBC, HPC#, IG%, IG#, Rct-He, immature platelet function (IPF)</td><td>— Plt-0, immature granulocytes (IG) %&#, reticulocyte hemoglobin (RET-He)</td></tr><tr><td>Differential method(s) used</td><td>fluorescent flow cytometry, RF/DC detecting method</td><td>fluorescent flow cytometry</td></tr><tr><td>Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • WBC</td><td>0-440/0-8 0-25/0-5,000 0-75 (Hct) <3%/<1.5% <1.0%/<4.0% <1.0% (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 agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs</td><td>0-310/0-8 0-25/0-5,000 0-60 (Hct) ≤3.0%/≤1.5% ≤1.5%/≤4.0% ≤1.5% (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 cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs</td></tr><tr><td>• RBC</td><td>cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro</td><td>cold agglut., severe microcytosis, frag. RBCs, leukocytosis</td></tr><tr><td>MCV or Hct</td><td>hemolysis Hct: cold agglut., leukocytosis, ABN red cell fragility, spherocytosis</td><td>Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis</td></tr><tr><td>• Platelet</td><td>pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts</td><td>(>100,000/μL) pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</td></tr><tr><td>• Hemoglobin</td><td>lipemia, ABN proteins, leukocytosis (>100,000/µL)</td><td>lipemia, ABN proteins, leukocytosis (>100,000/µL)</td></tr><tr><td>Interfering substances: differential</td><td>lyse-resistant RBCs</td><td>lyse-resistant RBCs</td></tr><tr><td>Age- and sex-specific reference ranges</td><td>yes</td><td>yes</td></tr><tr><td>Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib.</td><td>150/150 per analyzer on automation system once per year by FSR</td><td>80/80 once per year by FSR</td></tr><tr><td>Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed</td><td>open, closed, capillary/WBC, RBC, Hb, Hct, Plt two levels once every 24 hours (minimum CLIA)/none 130 μL/200 μL/1 mL</td><td>open, closed, capillary/— per CLIA requirements/none 85 μL/150 μL/1 mL</td></tr><tr><td>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</td><td>yes no yes yes >1,700/\$250,000</td><td>yes yes, XT-V product yes no</td></tr><tr><td>Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens • Stored in conjunction with CBC data • Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen and/or result info. displayed</td><td>yes yes 10,000 samples 10,000 samples; 20,000 orders 10,000 samples; 2 years plus, with optional decision logic software yes yes yes yes yes yes yes yes user and vendor yes yes yes yes</td><td>yes yes 10,000 samples 10,000 samples 10,000 samples yes yes yes yes yes yes yes yes yes y</td></tr><tr><td>LIS interface formats supported Information transferred on LIS interface</td><td>RS-232C/TCP IP numeric and flag results, histograms and scatterplots, patient demographics,</td><td>RS-232/TCP-IP, ASTM numeric and flag results, histograms and scatterplots, patient demographics,</td></tr><tr><td>LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features</td><td>orders yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments, multiple sites</td><td>orders yes contact vendor yes, Sysmex WAM (Work Area Manager) enhanced QC, data archiving, data collation from multiple instruments</td></tr><tr><td>Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per CLSI standard Auto2A</td><td>Roche, Labotix, IDS, A&T, Thermo engen Codabar, codes 39 and 128, interl. 2 of 5, ITF, NW7, EAN 8 and 13 yes</td><td>Codabar, codes 39 and 128, interl. 2 of 5, ITF, NW7, EAN 8 and 13 yes</td></tr><tr><td>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 Mftr. can perform diagnostics via modem</td><td>daily: <3 min (operator time) yes <24 hours yes/no yes, also via Internet</td><td>daily: <3 min yes <24 hours yes/no yes, also via Internet</td></tr><tr><td>Acquisition program based on cost-per-reportable result</td><td>yes</td><td>yes</td></tr><tr><td>Distinguishing features</td><td>high-throughput, flexible, scalable configurations available (>125 standard configurations available); platelet linearity—5 million; new parameters for platelet monitoring—IPF & retic Hb measurement & 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</td><td>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</td></tr><tr><td></td><td></td><td></td></tr></tbody></table>	

December 2009 CAP TODAY / 35

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Part 13 of 13	Sysmex America Inc. Tammy Kutz kutzt@sysmex.com 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa	Sysmex America Inc. Tammy Kutz kutzt@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 2008 No. units installed in U.S./outside U.S./list price	Sysmex XT-1800i 2002/2001/60 860/4,600/\$125,000	XS-1000i and XS-1000i AutoLoader (20 sample autoloader option) 2006/2005/300 935/5,000/\$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 %&# none Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity, NRBC, body fluids none none immature granulocytes (IG%&#)</td><td>standard menu (left) plus: MPV, RDW-SD, RDW-CV none Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast imm. gran., left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity, NRBC none none IG% research screen</td></tr><tr><td>Differential method(s) used</td><td>fluorescent flow cytometry</td><td>fluorescent flow cytometry</td></tr><tr><td>Linearity: • WBC count (10⁹/L)/RBC count (10¹²/L) • Hemoglobin (g/dL)/platelet (10⁹/L) • MCV (fL) or Hct (%) Precision: • WBC count/RBC count • Hemoglobin/platelet • MCV or Hct Accuracy of automated diff. compared with manual diff. (per CLSI H-20A), regression equation Interfering substances: • WBC • RBC • MCV or Hct • Platelet</td><td>$\begin{array}{l} 0-310/0-8\\ 0-25/0-5,000\\ 0-60 \text{ (Hct)}\\ \le 3.0\%/\le 1.5\%\\ \le 1.5\%/\le 4.0\%\\ \le 1.5\% \text{ (Hct)}\\ \text{neut% } \text{r=}0.95, \text{y=}0.95\text{x}+3.38; \text{ lymph% } \text{r=}0.96, \text{y=}0.85\text{x}+1.67; \text{mono% } \text{r=}0.90, \text{y=}11.37\text{x}+1.89; \text{eos% } \text{r=}0.94, \text{y=}0.87\text{x}+0.04; \text{baso% } \text{r=}0.76, \text{y=}0.48\text{x}+0.24\\ \text{cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs}\\ \text{cold agglut., severe microcytosis, frag. RBCs, leukocytosis}\\ \text{Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis}\\ \text{(>}100,000/\muL)\\ \text{pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts} \end{array}$</td><td>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 cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts</td></tr><tr><td>• Hemoglobin</td><td>lipemia, ABN proteins, leukocytosis (>100,000/μL)</td><td>lipemia, ABN proteins, leukocytosis (>100,000/μL)</td></tr><tr><td>Interfering substances: differential</td><td>lyse-resistant RBCs</td><td>lyse-resistant RBCs</td></tr><tr><td>Age- and sex-specific reference ranges Max. CBCs per hr/max. 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