SURVEY OF INSTRUMENTS

High-volume hematology analyzers

Part 1 of 9 *See related article, page 36*	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbott.com	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbott.com
Name of instrument	Cell-Dyn 3200	Cell-Dyn 3700
First year sold–installed in U.S./outside U.S.	1997/1997	1999/1999
No. units installed in U.S./outside U.S./list price	>700/>1,500/$165,000	>300/>500/$180,000 SL Model, $140,000 CS Model
Test menu: •Chartable	standard menu (left) plus: RDW, MPV	standard menu (left) plus: RDW, MPV, retic #&%, IRF
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	band #&%, IG #&%, variant lymph #&%, blast #&%, PCT, PDW, NRBC #&%	band, IG, variant lymph, blast, PCT, PDW, NRBC #&% and retic scatter profile
•Flags	band, IG, variant lymph, blast, NRBC, NWBC, RRBC, FWBC, RBC morph., high/low interp. message, LRI, URI, LURI, WBC	suspect populations, band, blast, variant lymph, IG, NRBC, RRBC, NWBC, LRI, URI, LURI, RBC morph., FWBC, high/low interp. message, WBC
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research-use-only	none	none
Tests unique to analyzer	3-dimensional optical RBC analysis with advanced MCV measurement	IRF
Differential method(s) used	MAPSS (Multi-Angle Polarized Scatter Sep.)	MAPSS (Multi-Angle Polarized Scatter Sep.)
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–250/0–8	0–250/0–8
•Hemoglobin (g/dL)/platelet (10^9/L)	0–25/0–1,750	0–24/0–2,000
•MCV (fL) or Hct (%)	35–180 (MCV)	50–200 (MCV)
Precision: •WBC count/RBC count	≤2.7%/≤1.5%	≤2.5%/≤1.5%
•Hb/platelet	≤1.0%/≤4.0%	≤1.2%/≤5.0%
•MCV or Hct	≤1.0% (MCV)	≤1.0% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	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, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs	NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs
•RBC	elevated WBC count, increased numbers of giant Plts, autoagglutination, in vitro hemolysis	increased No. giant Plts, autoagglutination, in vitro hemolysis
•MCV or Hct	MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased No. of giant Plts	MCV: elevated WBC count, increased No. giant Plts, hyperglycemia, in vitro hemolysis
•Platelet	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Plts	WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt clumps, increased No. giant Plts
•Hb	elevated WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs	increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs
Interfering substances: differential	n/a	n/a
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	78/78	90/90
Recommended average frequency of calib.	6 months verification	6 months
•Modes calibrated/parameters calibrated	open & closed/WBC, RBC, Hb, MCV, Plt, MPV	open & closed/WBC, RBC, Hb, MCV, Plt
Frequency of blood/latex controls	2 levels every 8 hrs/n/a	2 levels every 8 hrs/n/a
Min. specimen vol. open/closed/sample dead vol. closed	130 µL/250 µL/1 mL (sample loader)	130 µL/355 µL/1.0 mL
Tube sampling supported	yes	yes (13x75 mm)
Veterinary capability	no	yes
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	yes (flags only)
If auto. slidemaker available, No. installed/list price	80/$125,000	80/$125,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	10,000 results	10,000 results
Memory capacity—numeric results–No. specimens	10,000 results	10,000 results
Memory capacity—histo/cytograms–No. specimens	10,000 results	10,000 results
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	no
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 threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary	proprietary
Information transferred on LIS interface	numeric & flag results, histograms & 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	yes	yes
How labs get LOINC codes for reagent kits	package insert; www.e-abbott.com; 800-323-9100	package insert; www.e-abbott.com; 800-323-9100
Optional data mgmt. or collation system	yes; price TBD; proprietary	yes; price TBD; proprietary
• Software features	enhanced QC, data archiving, data collation from multiple instruments	enhanced QC, data archiving, data collation from multiple instruments
Interface avail. or planned to auto. specimen-handling system	Lab-Interlink, MDS/Autolab, Beckman Coulter (planned), Roche (planned), Labotix	Lab-Interlink (planned), MDS/AutoLab, Beckman Coulter (planned), Roche (planned), Labotix (planned)
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5	Codabar, codes 39 & 128, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 5 min; monthly: 10 min	daily: 30 sec; bi-weekly: 5 min; monthly: 10 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	average: <4 hrs	average: <4 hrs
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	in development	in development
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	MAPSS cell-by-cell analysis provides a better diff.; focused flow 2-D optical RBC and Plt analysis provides better separation between microcytic RBCs and large Plts; uses only 3 reagents; 3-D MCV	MAPSS cell-by-cell analysis provides a better diff.; retic with reportable IRF (immature retic. fraction); 60-species veterinary package

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

Survey editor: Raymond D. Aller, MD

High-volume hematology analyzers

Part 2 of 9	Abbott Diagnostics Hematology Business Unit 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbott.com	ABX Diagnostics Inc. Jim Mulry jmulry@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 x 259 www.abx.com
See related article, page 36		
Name of instrument	Cell-Dyn 4000	Pentra 60c+ Hematology Analyzer
First year sold–installed in U.S./outside U.S.	1997/1997	2000/2000
No. units installed in U.S./outside U.S./list price	>350/>500/$250,000	100/300/$49,500
Test menu: •Chartable	standard menu (left) plus: RDW, MPV, NRBC #&%, retic #&%, IRF, CD61 (immuno-Plt), CD 3/4, CD 3/8 (immuno T-cell)	standard menu (left) plus: RDW, MPV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	#&% for segs., bands, IG, blasts, variant lymph; PDW, PCT, white cell viability fraction (WVF)	atyp. lymph, atyp. lymph %, LIC, LIC %
•Flags	band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clump, ASYM, high/low interp. msg., PCT, PDW	operator selectable flagging
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research-use-only	none	none
Tests unique to analyzer	reportable NRBC #&%, CD61 for Plts, WVF, CD 3/4, CD 3/8 (immuno T-cell)	none
Differential method(s) used	optical scatter & fluorescence technology	DHSS technology combining cytochemistry, focused flow impedance, & light absorbance principles of measurement
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–250/0–8	0.1–90/0.5–8.1
•Hemoglobin (g/dL)/platelet (10^9/L)	1.0–25/0–2,000	2.5–23/10–1,000
•MCV (fL) or Hct (%)	37–197 (MCV)	10–70 (Hct)
Precision: •WBC count/RBC count	≤2.5%/≤1.5%	<5%/<3%
•Hb/platelet	≤1.0%/≤4.0%	<3%/<8%
•MCV or Hct	≤1.0% (MCV)	<3% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	%neut 0.94, %lymph 0.93, %mono 0.84, %eos 0.91, %baso 0.40, NRBC/WBC 0.91, retic 0.95	neut 0.99, lymph 0.98, mono 0.96, eos 0.89, baso 0.54
Interfering substances: •WBC	lyse-resistant RBCs, Plt clumps	NRBCs, Plt clumps, lyse-resistant RBCs
•RBC	autoagglutinins, cold agglutinins, hemolysis, small leukocytes (in cases where leukocyte count is high [>100 K/µL] and MCV is high)	cold agglutinins
•MCV or Hct	MCV: in vitro hemolysis, autoagglutinins, cold agglutinins, hyperglycemia, leukocytosis with macrocy. anemia	Hct: extreme leukocytosis
•Platelet	Plt clumps, WBC & RBC fragments, microcytic RBCs, autoagglutinins, cold agglutinins, Plt satellitosis	microcytes, Plt clumps
•Hb	high lipids (>700 mg/dL), high WBCs (>250 K/µL, based on concentrated, normal WBCs), high bilirubin (>33 mg/dL)	extreme lipemia/leukocytosis
Interfering substances: differential	n/a	NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	106/106	60/60
Recommended average frequency of calib.	6 months verification	6 months
•Modes calibrated/parameters calibrated	open-closed one proc./WBC, RBC, Hb, MCV, Plt, MPV	closed-open/WBC, RBC, Hb, HCT, Plt, MPV
Frequency of blood/latex controls	2 levels every 8 hrs/n/a	per CLIA standards/none
Min. specimen vol. open/closed/sample dead vol. closed	112.5 µL–aspir. vol./same/387 µL–dead vol.	53 µL/53 µL/0.5 mL
Tube sampling supported	yes	yes (multiple sizes)
Veterinary capability	no	yes
Microsample capability	yes (250 µL) in Sarstedt Multivette & Becton Dickinson Microtainer tubes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes (flags only)	no
If auto. slidemaker available, No. installed/list price	80/$125,000	—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes, with Hemalink Data Manager
Max. archived data accessible when system online	16,000 results	unlimited with Hemalink Data Manager
Memory capacity—numeric results–No. specimens	16,000 results	10,000, unlimited with Hemalink Data Manager
Memory capacity—histo/cytograms–No. specimens	16,000 results	10,000, unlimited with Hemalink Data Manager
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	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
Some results can be transmitted to LIS while others held	yes	yes
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary	ASTM 1394 & 1238, HL7, IEEE MIB
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, LIS to instrument—broadcast
LOINC codes transmitted with results	yes	yes
How labs get LOINC codes for reagent kits	www.e-abbott.com; package insert; 800-323-9100	—
Optional data mgmt. or collation system	yes; price TBD; proprietary	yes
• Software features	enhanced QC, data archiving, data collation from multiple instruments	enhanced QC, data archiving with Hemalink Data Manager
Interface avail. or planned to auto. specimen-handling system	Lab-Interlink, MDS/AutoLab, Beckman Coulter (planned), Roche (planned), Labotix (planned)	no
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5	Codabar, codes 39 & 128, ASTM, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 30 sec; weekly: 5 min; monthly: 10 min	weekly: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	average: <4 hrs	24 hrs
Onboard diagnostics/limited to software problems	yes/no	yes/yes
Mftr. can perform diagnostics via modem	in development	yes, with Hemalink Data Manager
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	reportable NRBC count; monoclonal antibody capability; fluorescent random access retic with reportable IRF; WBC viability index; Argon laser	reliable 5-part WBC diff. technology—MTBF over 200 days; small footprint; small sample size of 53 µL; Hemalink Data Manager

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SURVEY OF INSTRUMENTS

High-volume hematology analyzers

Part 3 of 9	ABX Diagnostics Inc. Jim Mulry jmulry@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 x 259 www.abx.com	ABX Diagnostics Inc. Jim Mulry jmulry@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 x 259 www.abx.com
See related article, page 36		
Name of instrument	Pentra 120 Retic Hematology Analyzer	Paros CRP/FDA CLEARANCE PENDING
First year sold–installed in U.S./outside U.S.	1999/1997	FDA CLEARANCE PENDING/80
No. units installed in U.S./outside U.S./list price	18/550/$125,000	0/150/$25,000
Test menu: •Chartable	standard menu (left) plus: RDW, IRF, MPV	standard menu (left) plus: CRP on whole blood
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	LIC, atyp. lymph, CRC%	CRP on whole blood
•Flags	operator selectable flagging	—
FDA-cleared tests but not clinically released	none	n/a
Tests not available but submitted for clearance	none	instrument 510(k) CLEARANCE PENDING
Tests in development	none	n/a
For research-use-only	none	n/a
Tests unique to analyzer	none	CRP on whole blood
Differential method(s) used	cytochemistry, focused flow impedance, light absorbence	linked to ABX hematology analyzers via Hemalink Data Manager
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–150/0.5–8.1	—/—
•Hemoglobin (g/dL)/platelet (10^9/L)	2–25/0–2,000	—/—
•MCV (fL) or Hct (%)	10–70 (Hct)	—
Precision: •WBC count/RBC count	<5%/<3%	—/—
•Hb/platelet	<3%/<8%	—/—
•MCV or Hct	<3% (Hct)	—
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut 0.99, lymph 0.99, mono 0.92, eos 0.97, baso 0.71	—
Interfering substances: •WBC	NRBCs, Plt clumps/lyse-resistant RBCs	—
•RBC	cold agglutinins	—
•MCV or Hct	Hct: extreme leukocytosis	
•Platelet	microcytes, Plt clumps	—
•Hb	extreme lipemia/leukocytosis	—
Interfering substances: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	—
Age- and sex-specific reference ranges	yes	—
Max. CBCs per hr/max. CBCs & diffs. per hr	120/120	CRP 13 tests per hr/—
Recommended avg. frequency of calib.	6 months	—
•Modes calibrated/parameters calibrated	closed, open/WBC, RBC, Hb, Hct, Plt	—/—
Frequency of blood/latex controls	per CLIA standards/not required	—/—
Min. specimen vol. open/closed/sample dead vol. closed	130 µL/200 µL/1 mL	—/—/—
Tube sampling supported	yes	—
Veterinary capability	yes	—
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	no
If auto. slidemaker available, No. installed/list price	price $40,000	—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	90,000, unlimited with Hemalink Data Manager	unlimited with Hemalink Data Manager
Memory capacity—numeric results–No. specimens	90,000, unlimited with Hemalink Data Manager	unlimited with Hemalink Data Manager
Memory capacity—histo/cytograms–No. specimens	90,000, unlimited with Hemalink Data Manager	unlimited with Hemalink Data Manager
•Stored in conjunction with CBC data	yes	—
•Histo/cytogram images & CBC data printed as 1 report	yes	—
Saved results can be recalled and retransmitted	yes	—
Saved data can be sorted for reprocessing or report transmission	yes	—
Performs delta checks	yes	—
Tags and holds results for followup, confirm. testing, or rerun	yes	—
Parameters for flags for holding samples are defined by	user	—
Some results can be transmitted to LIS while others held	yes (operator programmable)	—
Scattergram display: cell-specific color	no	—
Histogram display: color with threshhold	yes	—
Choice of desired specimen &/or result info. displayed	yes	—
LIS interface formats supported	proprietary, ASTM 1394 & 1238, HL7, IEEE MIB	—
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics & orders	—
LOINC codes transmitted with results	no	—
How labs get LOINC codes for reagent kits	—	—
Optional data mgmt. or collation system	yes	yes, ABX Diagnostics
• Software features	enhanced QC, data archiving (Hemalink Data Manager), data collation from multiple instruments	enhanced QC, data archiving, data collation from multiple instruments, one interface (LIS) for multiple ABX instruments
Interface avail. or planned to auto. specimen-handling system	no	n/a
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5	—
Accommodates bar-code placement per NCCLS standard Auto2A	yes	—
Time required for maintenance by lab personnel	weekly: 10 min; monthly: 10 min	weekly: 15 min
Onboard maintenance records	yes	—
Time from communication of problem to engineer on site	4 hrs average, 24 hrs guaranteed	—
Onboard diagnostics/limited to software problems	yes/yes	—
Mftr. can perform diagnostics via modem	yes, with Hemalink Data Manager	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	automatic repeats for sample verification; MTBF>90 days; small footprint; integrated reticulocyte methodology and slidemaker/stainer; thiazole orange reticulocyte methodology	small sample size (8 µL) whole blood CRP (EDTA tube/serum); combined CBC; diff. and whole blood CRP (no centrifugation required)

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High-volume hematology analyzers

Part 4 of 9 *See related article, page 36*	Bayer Diagnostics Nancy Lavon nancy.lavon.b@bayer.com 555 White Plains Rd. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com	Bayer Diagnostics Nancy Lavon nancy.lavon.b@bayer.com 555 White Plains Rd. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com
Name of instrument	Advia 120 Hematology System	Advia 70
First year sold–installed in U.S./outside U.S.	1998/1998	2001/2001
No. units installed in U.S./outside U.S./list price	700/3,000/$169,000–$189,000	—/—/$89,000
Test menu: •Chartable	standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono	standard menu (left) plus: RDW, MPV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	%: hypo, hyper, macro, micro; calc. Hb, MPXI; %: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost count	none
•Flags	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	diff., WBC, N, B, L, RBC, ABN, PL, CI, Plt/RBC
FDA-cleared tests but not clinically released	none	—
Tests not available but submitted for clearance	none	—
Tests in development	IRF, MPC, MPM	—
For research-use-only	CSF, eos	Pct, PDW
Tests unique to analyzer	CHCM, HDW, CHr, CHCMr, MPC, MPM; CSF: WBC, RBC, PMN, neut, lymph, mono	—
Differential method(s) used	perox–peroxidase cytochem. staining with light scatter & absorption; baso–cytochem. stripping with 2-angle laser light scatter	optical & enhanced impedance
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0.02–400/0–7.0; CSF WBC 0–5,000/µL; CSF RBC 0–1,500/µL	0.1–99/0.02–9.99
•Hemoglobin (g/dL)/platelet (10^9/L)	0-22.5 /5-3,500	1.5–30/10–2,000
•MCV (fL) or Hct (%)	30–180 (MCV)	30–150 (MCV)
Precision: •WBC count/RBC count	2.7%/1.2%	2.0%/1.2%
•Hb/platelet	0.93%/2.93%	1.0%/3–10%
•MCV or Hct	0.78% (MCV)	1.0% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut 0.997r, lymph 0.997r, mono 0.943r, eos 0.979r, baso 0.772r, luc 0.944r	neut% r>0.9, lymph% r>0.9, mono% >0.7, eos% r>0.8, baso% >0.5
Interfering substances: •WBC	incomplete RBC lysis (perox only)	incomplete RBC lysis
•RBC	cold agglutinins, extreme sickle cell	cold agglutinins
•MCV or Hct	none	extremely high white blood cell count (HCT)
•Platelet	none	RBC fragments
•Hb	high WBC, lip., extremely high bili., interfere with cyanmethb. only, none with direct cellular Hb (CHCM)	lipemia, elevated WBC
Interfering substances: differential	incomplete lysis of RBCs, complete myeloperox. deficiency	NRBCs, unlysed RBC, platelet clumps
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	120/120	70/70
Recommended avg. frequency of calib.	6 months	every 6 months per governmental requirements
•Modes calibrated/parameters calibrated	open, closed, autosampler/all measured params	open & closed/all measured parameters
Frequency of blood/latex controls	once per shift/not required	one level per shift/not required
Min. specimen vol. open/closed/sample dead vol. closed	157 µL/157 µL/<300 µL (tube size dependent)	90 µL/180 µL/120 µL
Tube sampling supported	yes (2, 3, 5, 7 mL—all sizes–open tube)	yes (12x75)
Veterinary capability	yes	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes	yes
If auto. slidemaker available, No. installed/list price	Advia S60, just released/$35,000	Advia S60, just released/$35,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	no	yes
Max. archived data accessible when system online	10,000 samples	100,000
Memory capacity—numeric results–No. specimens	10,000	100,000
Memory capacity—histo/cytograms–No. specimens	10,000	100,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	no
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
Some results can be transmitted to LIS while others held	yes	all results for that sample are transmitted at once
Scattergram display: cell-specific color	yes	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary (Spec 79)	proprietary, ASTM 1394, E 1381
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast; host query for demographics & orders	numeric & flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument— broadcast
LOINC codes transmitted with results	no	—
How labs get LOINC codes for reagent kits	online documentation	online documentation
Optional data mgmt. or collation system	in development	in development
• Software features		
Interface avail. or planned to auto. specimen-handling system	MXS (Japan), LabCell (Bayer)	—
Bar-code symbologies read on tube	Codabar, codes 39 & 128, ASTM, interl. 2 of 5	Codabar, code 39, interl. 2 of 5
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 15 min; weekly: 15 min; monthly: 15 min	daily: 0; weekly: 0; monthly: 20 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	territory dependent	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	in development
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	unique laser technology provides cellular Hb for RBCs and retics; 2-D Plt analysis that eliminates interference from RBC fragments and exclusion of large Plts; dual WBC counts with a linearity of up to 400,000; CSF assay	microsampling; auto recount; dual WBCs; automatic wakeup and shutdown; no daily or weekly maintenance

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

SURVEY OF INSTRUMENTS

High-volume hematology analyzers

Part 5 of 9 *See related article, page 36*	Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com	Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com
Name of instrument	Coulter LH 700 Series	Coulter Gen•S System
First year sold–installed in U.S./outside U.S.	2001	1996
No. units installed in U.S./outside U.S./list price	300/500/LH 750: $195,000; LH 755: $367,500	>1,200/>2,000/$177,500; with slidemaker-stainer, $327,000
Test menu: •Chartable	standard menu (left) plus: RDW, MPV, retic #&%, IRF, MPV, graded RBC morph, NRBC %&#	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., MRV, IRF
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	PCT, PDW	PCT, PDW
•Flags	user-definable age-, gender-, &/or location-based ref.; intervals, action & critical limits; user-def. RBC morph.; gradient msgs. (=+, ++, +++); user-selectable sensitivity for diff. abnormal population suspect messages	user-definable age-, gender- &/or location-based ref. intervals, action & critical limits; user-def. RBC morph. gradient msgs. (=+, ++, +++); user-selectable sensitivity for diff. abnormal population suspect messages
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	—
Tests in development	body fluids	none
For research-use-only	high light scatter retics, mean spherical cell volume	high light scatter retics, mean spherical cell volume
Tests unique to analyzer	NRBC, mean spherical cell volume	mean spherical cell volume
Differential method(s) used	Coulter's 3-D VCS technology, AccuFlex technology with IntelliKinetics & AccuGate	Coulter's 3-D VCS technology, AccuFlex technology with IntelliKinetics & AccuGate
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–400/0–8.0	0–140/0–8.0
•Hemoglobin (g/dL)/platelet (10^9/L)	0–25/0–3,000	0–25/0–1,500
•MCV (fL) or Hct (%)	50–200 (MCV)	50–200 (MCV)
Precision: •WBC count/RBC count	<1.7%/<0.8%	<1.7%/<0.8%
•Hb/platelet	<0.8%/<3.3%	<0.8%/<3.3%
•MCV or Hct	<0.8% (MCV)	<0.8% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	lymph%= ±1.5%, neut%= ±2.0%, mono%= ±1.0%, eos%= ±0.5%, baso%= ±0.5%	lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0%
Interfering substances: •WBC	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt
•RBC	very high WBC, high conc. large Plt, autoagglutinins	very high WBC, high conc. large Plt, autoagglutinins
•MCV or Hct	MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins	MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins
•Platelet	very small RBCs & WBC frags. may interfere	very small RBCs & WBC frags. may cause no-fit
•Hb	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
Interfering substances: differential	high triglycerides may affect lysing	high triglycerides may affect lysing
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	105/105	105/105
Recommended avg. frequency of calib.	2 times per yr	2 times per yr
•Modes calibrated/parameters calibrated	primary/RBC, WBC, Hb, MCV, Plt, MPV	primary/RBC, WBC, Hb, MCV, Plt, MPV
Frequency of blood/latex controls	once per shift/once per day	once per shift/once per day
Min. specimen vol. open/closed/sample dead vol. closed	200 µL/300 µL/550 µL with slidemaker/1.0 mL	200 µL/300 µL/550 µL with slidemaker/1.0 mL
Tube sampling supported	yes (multiple sizes & styles)	yes (multiple sizes & styles)
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	yes, both	yes, both
If auto. slidemaker available, No. installed/list price	>200 U.S./—	>200 U.S./—
Archives patient data for later comparison	yes	yes
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	20,000 samples	20,000 samples
Memory capacity—numeric results–No. specimens	20,000	20,000
Memory capacity—histo/cytograms–No. specimens	5,000	5,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	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 threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232, proprietary	RS-232, proprietary
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with results	no	no
How labs get LOINC codes for reagent kits	technical support	technical support
Optional data mgmt. or collation system	yes	yes
• Software features	enhanced QC, data archiving, common database, extensive decision rules, delta checking	enhanced QC, data archiving, common database, extensive decision rules, delta checking
Interface avail. or planned to auto. specimen-handling system	Beckman Coulter	—
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, NW-7	Codabar, codes 39 & 128, interl. 2 of 5, NW-7
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	monthly: 2 min	monthly: 2 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	—	—
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	extensive decision support; enumeration of NRBCs with every differential; random access; automation ready; extended linearity for WBC and platelets using AccuCount Technology; integrated slidemaker/staining options	VCS technology; lowest review rate in class; no daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart, AccuGate, AccuFlex, IntelliKinetics application; WBC in near native state; 3-D diff. display; online training and help

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

High-volume hematology analyzers

Part 6 of 9 *See related article, page 36*	Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com	Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com
Name of instrument	Coulter HmX	Coulter Maxm with Reticulocytes
First year sold–installed in U.S./outside U.S.	1999 HmX AL, 1999 HmX CP	1991 Maxm; 1992 Maxm AL
No. units installed in U.S./outside U.S./list price	>400/>600/$135,000 AL; $120,000 CP	>1,500/>2,000/Maxm with Retics $90,000; Maxm AL with Retics $105,000
Test menu: •Chartable	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV	standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph.
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	PCT, PDW	PCT, PDW
•Flags	comprehensive high/low, definitive & suspect messages	comprehensive high/low, definitive & suspect messages
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research-use-only	none	mean retic volume, maturation index
Tests unique to analyzer	none	none
Differential method(s) used	Coulter's 3-D VCS technology	Coulter's 3-D VCS technology
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–99.9/0–7.0	0–99.9/0–7.0
•Hemoglobin (g/dL)/platelet (10^9/L)	0–25/0–999	0–25/0–999
•MCV (fL) or Hct (%)	50–150 (MCV)	50–150 (MCV)
Precision: •WBC count/RBC count	<2.5%/<2.0%	<2.5%/<2.0%
•Hb/platelet	<1.5%/<5.0%	<1.5%/<5.0%
•MCV or Hct	<2.0% (MCV)	<2.0% (MCV)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0%	lymph%= ±3.0%, mono%= ±2.0%, neut%= ±3.0%, eos%= ±1.0%, baso%= ±1.0%
Interfering substances: •WBC	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt	unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt
•RBC	very high WBC, high conc. of very large Plt, autoagglutinins	very high WBC, high conc. of very large Plt, autoagglutinins
•MCV or Hct	MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins	MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins
•Platelet	very small RBCs & WBC frags. may cause no-fit	very small RBCs & WBC frags. may cause no-fit
•Hb	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs	very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs
Interfering substances: differential	high triglycerides may affect lysing	high triglycerides may affect lysing
Age- and sex-specific reference ranges	gender-specific printout	gender-specific printout
Max. CBCs per hr/max. CBCs & diffs. per hr	75/75	75/75
Recommended average frequency of calib.	2 times per yr	4 times per yr
•Modes calibrated/parameters calibrated	primary/RBC, WBC, Hb, MCV, Plt, MPV	primary/RBC, WBC, Hb, MCV, Plt, MPV
Frequency of blood/latex controls	once per shift/once per day	once per shift/once per day
Min. specimen vol. open/closed/sample dead vol. closed	125 µL/185 µL/50 µL predilute/0.5 mL	125 µL/185 µL/50 µL predilute/0.5 mL
Tube sampling supported	yes (multiple sizes & styles)	yes (multiple sizes & styles)
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	no
If auto. slidemaker available, No. installed/list price	n/a	n/a
Archives patient data for later comparison	yes	no
Patient-specific archiving	yes	yes
Max. archived data accessible when system online	5,000 samples	5,000 samples
Memory capacity—numeric results–No. specimens	5,000	5,000
Memory capacity—histo/cytograms–No. specimens	5,000	5,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	no
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, through a selective batch process	no (all held)
Scattergram display: cell-specific color	4 colors/cell types	4 colors/cell types
Histogram display: color with threshhold	colors without thresholds	colors without thresholds
Choice of desired specimen &/or result info. displayed	no	no
LIS interface formats supported	RS-232, proprietary	RS-232, proprietary
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with results	no	no
How labs get LOINC codes for reagent kits	technical support	technical support
Optional data mgmt. or collation system	yes	yes
• Software features	enhanced QC, data archiving, common database, extensive decision rules, delta checking	enhanced QC, data archiving, common database, extensive decision rules, delta checking
Interface avail. or planned to auto. specimen-handling system	Beckman Coulter	Beckman Coulter
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, NW-7	Codabar, codes 39 & 128, interl. 2 of 5, NW-7
Accommodates bar-code placement per NCCLS standard Auto2A	no	no
Time required for maintenance by lab personnel	monthly: 2 min	monthly: 2 min
Onboard maintenance records	no	no
Time from communication of problem to engineer on site	—	—
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	no	no
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	VCS technology; lowest review rate in class; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single sample models	VCS technology; lowest review rate in class; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; autoloader and single sample models

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

SURVEY OF INSTRUMENTS

High-volume hematology analyzers

Part 7 of 9 *See related article, page 36*	Beckman Coulter Inc. Martha M. Diaz/Cellular Analysis Marketing 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8847 www.beckmancoulter.com	Roche Diagnostics Corp. Andy Hay 9115 Hague Rd. Indianapolis, IN 46250-0475 800-428-5074 www.roche.com
Name of instrument	Coulter Ac•T 5diff Family	Sysmex XE-2100
First year sold–installed in U.S./outside U.S.	2001/2000	2000
No. units installed in U.S./outside U.S./list price	400/600/$43,500 cap pierce model; $38,500 open vial model	200/1,000/$225,000
Test menu: •Chartable	standard menu (left) plus: RDW, MPV	standard menu (left) plus: NRBC %&#, retic %&#*, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW	none
•Flags	complete operator selectable flagging	Plt clumps, RBC agglut, turbidity, WBC ABN scattergram, RBC ABN distrib., Plt ABN distrib., RBC lyse resistance, blasts, immature grans, left shift, atyp. lymph., ABN lymph./blast., ret ABN scattergram
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	IG %&#
For research-use-only	PCT, PDW, IMM, ATL	P-LCR, PCT, PDW
Tests unique to analyzer	none	NRBC, HPC#
Differential method(s) used	A^{c}V technology combining cytochemistry, focused flow impedance, and light absorbance prinicples of measurement	fluorescent flow cytometry, RF/DC detecting method
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0.4–91.3/0.23–7.7*	0–170/0–8
•Hemoglobin (g/dL)/platelet (10^9/L)	0–22/3.3–1,017*	0–25/0–5,000
•MCV (fL) or Hct (%)	1.8–63.8 (Hct)*	0–60 (Hct)
Precision: •WBC count/RBC count	<2%/<2%	<3%/<1.5%
•Hb/platelet	<1%/<5%	<1.0%/<4.0%
•MCV or Hct	<1.0% (MCV)	<1.0% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	not available in NCCLS H-20A format	neut% R=0.95, lymph% R=0.95, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96
Interfering substances: •WBC	NRBCs, Plt clumps, large Plts, lyse-resistant RBCs	cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs in patients with hemoglobinopathies, severe liver disease, or neonates
•RBC	cold agglutinins, Plt clumps, WBC overlinearity	cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis
•MCV or Hct	Hct: lipemic samples, high WBC, cold aggluts	Hct: cold agglutinins, leukocytosis (>100,000/µL), ABN red cell fragility, spherocytosis
•Platelet	RBC and WBC fragments	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts
•Hb	elevated WBC, lipemia	lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/µL)
Interfering substances: differential	lyse-resistant RBCs, NRBCs, lipemia	lyse-resistant RBCs
Age- and sex-specific reference ranges	yes	yes
Max. CBCs per hr/max. CBCs & diffs. per hr	60/60	150/150
Recommended average frequency of calib.	6 months	annually
•Modes calibrated/parameters calibrated	open/RBC, WBC, Hb, Hct, Plt	open, closed, capillary/WBC, RBC, Hb, Hct, Plt
Frequency of blood/latex controls	daily/none	per CLIA requirements/not required
Min. specimen vol. open/closed/sample dead vol. closed	30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC-diff/53 µL for CBC-diff./varies by tube size	130 µL/200 µL/1 mL
Tube sampling supported	yes (multiple sizes)	yes
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	yes with Alpha or HST upgrade
If auto. slidemaker available, No. installed/list price	n/a	>1,000
Archives patient data for later comparison	yes	yes
Patient-specific archiving	no	yes
Max. archived data accessible when system online	10,000 samples	10,000 samples
Memory capacity—numeric results–No. specimens	10,000	10,000
Memory capacity—histo/cytograms–No. specimens	10,000	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	no	yes
Tags and holds results for followup, 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, through user-defined criteria	yes
Scattergram display: cell-specific color	no	yes
Histogram display: color with threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	proprietary	RS-232C/TCP IP
Information transferred on LIS interface	numeric & flag results, histograms & diff. plots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders
LOINC codes transmitted with results	no	—
How labs get LOINC codes for reagent kits	technical support	—
Optional data mgmt. or collation system	yes	yes, proprietary
• Software features	enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delta checking	enhanced QC, data archiving, data collation from multiple instruments, online QC
Interface avail. or planned to auto. specimen-handling system	no	Roche, Labotix, IDS, A&T
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, EAN 8 & 13	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW-7, EAN 8 & 13
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	weekly: 5 min	daily: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	—	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	no	yes
Acquisition program based on cost-per-reportable result	no	yes
Distinguishing features	quant. 5-part WBC diff. instrument lists for <$40,000; aspirates only 30 µL of sample; requires small space footprint and runs quietly ** linearity stated for Ac•T 5diff CP*	enumeration of NRBCs; throughput of 150 CBCs per hour; random access; discrete testing; extended linearities; HPC testing; online QC; remote diagnostics

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

High-volume hematology analyzers

Part 8 of 9 *See related article, page 36*	Roche Diagnostics Corp. Andy Hay 9115 Hague Rd. Indianapolis, IN 46250-0475 800-428-5074 www.roche.com	Roche Diagnostics Corp. Andy Hay 9115 Hague Rd. Indianapolis, IN 46250-0475 800-428-5074 www.roche.com
Name of instrument	Sysmex XE-2100L	Sysmex XE-2100 Alpha/HST
First year sold–installed in U.S./outside U.S.	2001	2000
No. units installed in U.S./outside U.S./list price	25/100/$200,000	>1,000 worldwide/$360,000–$1,000,000
Test menu: •Chartable	standard menu (left) plus: MPV, RDW-SD, RDW-CV, NRBC %&#, HPC#	standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	none	none
•Flags	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	Plt clumps, RBC agglut., turbidity, WBC ABN scattergram, RBC ABN distrib., Plt ABN distrib., RBC lyse resistance, blasts, immature grans., left shift, atyp. lymph., ABN lymph./blast, ret. ABN scattergram
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	IG %&#
For research-use-only	IG%&#	P-LCR, PCT, PDW
Tests unique to analyzer	HPC#, NRBC	NRBC, HPC#
Differential method(s) used	fluorescent flow cytometry, RF/DC detecting method	fluorescent flow cytometry, RF/DC detecting method
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–170/0–8	0–170/0–8
•Hemoglobin (g/dL)/platelet (10^9/L)	0–25/0–5,000	0–25/0–5,000
•MCV (fL) or Hct (%)	0–60 (Hct)	0–60 (Hct)
Precision: •WBC count/RBC count	≤3%/≤1.5%	<3%/<1.5%
•Hb/platelet	≤1.0%/≤4.0%	<1.0%/<4.0%
•MCV or Hct	≤1.0% (Hct)	<1.0% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% R=0.95, lymph% R=0.96, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96	neut% R=0.95, lymph% R=0.95, mono% R=0.79, eos% R=0.92, baso% R=0.82, NRBC% R=0.96
Interfering substances: •WBC	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs	cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs in patients with hemoglobinopathies, severe liver disease, or neonates
•RBC	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)	cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis
•MCV or Hct	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)	Hct: cold agglut., leukocytosis (>100,000/µL), ABN red cell fragility, spherocytosis
•Platelet	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts
•Hb	lipemia, ABN proteins, leukocytosis (>100,000/µL)	lipemia, ABN proteins in blood plasma, severe 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	150/600
Recommended average frequency of calib.	annually	annually
•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 CLIA requirements/not required	per CLIA requirements/not required
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 slide prep	no	yes
If auto. slidemaker available, No. installed/list price	—	>1,000/$250,000
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
Memory capacity—histo/cytograms–No. specimens	10,000	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	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 threshhold	yes	yes
Choice of desired specimen &/or result info. displayed	yes	yes
LIS interface formats supported	RS-232C/TCP IP	RS-232C/TCP IP
Information transferred on LIS interface	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders	numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders
LOINC codes transmitted with results	no	—
How labs get LOINC codes for reagent kits	n/a	n/a
Optional data mgmt. or collation system	yes, proprietary	yes, proprietary
• Software features	enhanced QC, data archiving, data collation from multiple instruments, online QC	enhanced QC, data archiving, data collation from multiple instruments, online QC
Interface avail. or planned to auto. specimen-handling system	Lab Interlink, MDS/AutoLab, Beckman Coulter, Roche, Labotix, A&T	Roche, Labotix, IDS, A&T
Bar-code symbologies read on tube	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW-7, EAN 8 & 13	Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW-7, EAN 8 & 13
Accommodates bar-code placement per NCCLS standard Auto2A	yes	yes
Time required for maintenance by lab personnel	daily: 15 min	daily: 15 min
Onboard maintenance records	yes	yes
Time from communication of problem to engineer on site	territory dependent	territory dependent
Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	remote diagnostics; online QC; random access; HPC testing; 150 CBC per hour throughput; discrete testing; NRBC enumeration	multiple configurations available as are all distinguishing features of the XE-2100

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High-volume hematology analyzers

Part 9 of 9 *See related article, page 36*	Roche Diagnostics Corp. Andy Hay 9115 Hague Rd. Indianapolis, IN 46250-0475 800-428-5074 www.roche.com	Roche Diagnostics Corp. Andy Hay 9115 Hague Rd. Indianapolis, IN 46250-0475 800-428-5074 www.roche.com
Name of instrument	Sysmex XT-2000i	Sysmex XT-1800i
First year sold–installed in U.S./outside U.S.	2002	2002
No. units installed in U.S./outside U.S./list price	30/100/$145,000	15/50/$125,000
Test menu: •Chartable	standard menu (left) plus: retic %&#, IRF, Plt-O, MPV, RDW-SD, RDW-CV	standard menu (left) plus: MPV, RDW-SD, RDW-CV
All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Laboratory	none	none
•Flags	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, ret ABN scattergram, NRBC	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
FDA-cleared tests but not clinically released	none	none
Tests not available but submitted for clearance	none	none
Tests in development	none	none
For research-use-only	IG%&#	IG%&#
Tests unique to analyzer	Plt-O	—
Differential method(s) used	fluorescent flow cytometry	fluorescent flow cytometry
Linearity: •WBC count (10^9/L)/RBC count (10^{12}/L)	0–310/0–8	0–310/0–8
•Hemoglobin (g/dL)/platelet (10^9/L)	0–25/0–2,000	0–25/0–2,000
•MCV (fL) or Hct (%)	0–60 (Hct)	0–60 (Hct)
Precision: •WBC count/RBC count	≤3.0%/≤1.5%	≤3.0%/≤1.5%
•Hb/platelet	≤1.5%/≤4.0%	≤1.5%/≤4.0%
•MCV or Hct	≤1.5% (Hct)	≤1.5% (Hct)
Accuracy of automated diff. compared with manual diff., per NCCLS H-20A	neut% R=0.95, lymph% R=0.96, mono% R=0.90, eos% R=0.94, baso% R=0.76	neut% R=0.95, lymph% R=0.96, mono% R=0.90, eos% R=0.94, baso% R=0.76
Interfering substances: •WBC	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs	cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs
•RBC	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)	cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/µL)
•MCV or Hct	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)	Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL)
•Platelet	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts	pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts
•Hb	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	80/80	80/80
Recommended average frequency of calib.	annually	annually
•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 CLIA requirements/not required	per CLIA requirements/not required
Min. specimen vol. open/closed/sample dead vol. closed	85 µL/150 µL/1 mL	85 µL/150 µL/1 mL
Tube sampling supported	yes	yes
Veterinary capability	no	no
Microsample capability	yes	yes
Prepares microscopic slides automatically or flags problems for slide prep	no	no
If auto. slidemaker available, No. installed/list price	—	—
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	10,000
•Stored in conjunction with CBC data	yes	yes
•Histo/cytogram images & CBC data printed as 1 report	yes	yes
Saved results can be recalled and retransmitted	yes	yes
Saved data can be sorted for reprocessing or report transmission	yes	yes
Performs delta checks	yes	yes
Tags and holds results for followup, confirm. testing, or rerun	yes	yes
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Onboard diagnostics/limited to software problems	yes/no	yes/no
Mftr. can perform diagnostics via modem	yes	yes
Acquisition program based on cost-per-reportable result	yes	yes
Distinguishing features	remote diagnostics; online QC; random access; fluorescent optical platelets; discrete testing	remote diagnostics; online QC; random access; discrete testing

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