## Hematology analyzers

# Aiming to ease lab labor, cost, TAT pressures

### Anne Ford

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

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

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

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

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

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

*Anne Ford is a writer in Chicago.*

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|---|---|
| Part 1 of 11 | Abbott Hematology<br>David Overcash<br>5440 Patrick Henry Dr.<br>Santa Clara, CA 95054<br>800-933-5535<br>www.abbottdiagnostics.com |
| **Name of instrument** | **CELL-DYN Sapphire** |
| First year installed in U.S./outside U.S./No. of units sold in 2006 | 2005/2005/618 |
| No. units installed in U.S./outside U.S./list price | 179/439/$250,000 |
| **Test menu:** <br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | |
| •Chartable | standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8 |
| •Laboratory | — |
| •Flags | band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clmp, ASYM, FP, CD61 agg., clot detected during aspiration, short sample |
| FDA-cleared tests but not clinically released | none |
| Tests not available but submitted for clearance | none |
| Tests in development | body fluid assay, optical RBC morphology |
| For research use only | none |
| Tests unique to analyzer | CD61 for Plts, WVF, CD3/4, CD3/8 (immuno T-cell) |
| **Differential method(s) used** | optical scatter & 3-color fluorescence |
| **Linearity:** •WBC count ($10^9$/L)/RBC count ($10^{12}$/L) | $0.4–250.0 \times 10^3$ μL / $0.22–7.50 \times 10^6$ μL |
| •Hemoglobin (g/dL)/platelet ($10^9$/L) | 1.0–24.8 g/dL (cyanide free)/$11.0–2,000.0 \times 10^3$ μL |
| •MCV (fL) or Hct (%) | 37.0–179 fL (MCV) |
| **Precision:** •WBC count/RBC count | ≤2.7%/≤1.5% |
| •Hb/platelet | ≤1.0%/≤4.0% |
| •MCV or Hct | ≤1.0% (MCV) |
| **Accuracy of automated diff. compared with manual diff.** (per NCCLS H-20A), regression equation | neut% r=0.942 slope 0.947 y=0.446; lym% r=0.936 slope=0.943 y=2.811; mono% r=0.623 slope=1.057 y=0.851; eos% r=0.446 slope=1.024 y=0.288; baso% r=0.232 slope=0.257 y=0.350 |
| **Interfering substances:** •WBC | Plt clumps, neut aggregates, Hb C crystals, lyse-resist. RBCs, cryoglob., cryofibr., frag. WBC, nRBC |
| •RBC | autoagg., cold agg., giant Plts, hemolysis, sm WBC |
| •MCV or Hct | MCV: autoagg., cold agg., elevated WBC, giant Plt, hemolysis, hyperglycemia |
| •Platelet | auto & cold agg., cryoglob., cryofibrin., giant Plt, micro RBC, Plt clumps, RBC frag., WBC frag., Plt satellitism |
| •Hb | lipids>700 mg/dL, WBCs>$250 \times 10^9$/L, bilirubin>33 mg/dL, Hb crystals |
| Interfering substances: differential | see WBC |
| Age- and sex-specific reference ranges | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 106/106 |
| Recommended average frequency of calib. | 6 months verification |
| •Modes calibrated/parameters calibrated | open-closed single procedure/WBC, RBC, Hb, Plt, MPV |
| Frequency of blood/latex controls | per regulatory requirement/n/a |
| Min. specimen vol. open/closed/sample dead vol. closed | 117 μL/117 mL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes |
| Tube sampling supported | yes (11.5–13 × 65-75 mm, 10.25 × 64 mm, 8.5 × 66 mm [Sarstedt Monovette]) |
| Veterinary capability | no |
| Microsample capability | yes |
| Prepares microscopic slides automatically or flags problems for slide prep | yes (flags only) |
| If auto. slidemaker available, No. installed/list price | n/a/$125,000 |
| Archives patient data for later comparison | yes |
| Patient-specific archiving | yes |
| Max. archived data accessible when system online | 10,000 results |
| Memory capacity—numeric results–No. specimens | 10,000 results |
| Memory capacity—histo/cytograms–No. specimens | 10,000 results |
| •Stored in conjunction with CBC data | yes |
| •Histo/cytogram images & CBC data printed as 1 report | yes |
| Saved results can be recalled and retransmitted | yes |
| Saved data can be sorted for reprocessing or report transmission | yes |
| Performs delta checks | yes |
| Tags and holds results for followup, confirm. testing, or rerun | yes |
| Parameters for flags for holding samples are defined by | user or vendor |
| Some results can be transmitted to LIS while others held | yes |
| Scattergram display: cell-specific color | yes |
| Histogram display: color with threshold | yes |
| Choice of desired specimen &/or result info. displayed | yes |
| LIS interface formats supported | ASTM 1394 |
| Information transferred on LIS interface | numeric & flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders |
| LOINC codes transmitted with results | no |
| How labs get LOINC codes for reagent kits | n/a |
| Optional data mgmt. or collation system | yes, multiple |
| •Software features | enhanced QC, data archiving, data collation from multiple instruments, remote viewing |
| Interface avail. or planned to auto. specimen-handling system | Accelerator APS |
| Bar-code symbologies read on tube | Codabar, codes 39 & 128, interl. 2 of 5 |
| Accommodates bar-code placement per NCCLS standard Auto2A | yes |
| Time required for maintenance by lab personnel | daily: 30 sec; weekly: 10 min; monthly: 5 min |
| Onboard maintenance records | yes |
| Time from communication of problem to engineer on site | — |
| Onboard diagnostics/limited to software problems | yes/no |
| Mftr. can perform diagnostics via modem | no |
| Acquisition program based on cost-per-reportable result | yes |
| **Distinguishing features** | 4 optical and 3 fluorescent detectors providing Multiple Scatter-plot Analysis; 2-D optical platelets that avoid interferences; fluorescent analysis of reticulocytes, nRBCs, and 3-color monoclonal analysis on a routine hematology analyzer |

# Hematology analyzers

| Part 2 of 11 | Abbott Hematology<br>**Deborah Archer** deborah.archer@abbott.com<br>5440 Patrick Henry Dr.<br>Santa Clara, CA 95054<br>800-933-5535<br>www.abbottdiagnostics.com | Abbott Hematology<br>**Deborah Archer** deborah.archer@abbott.com<br>5440 Patrick Henry Dr.<br>Santa Clara, CA 95054<br>800-933-5535<br>www.abbottdiagnostics.com |
|---|---|---|
| **Name of instrument**<br>First year installed in U.S./outside U.S./No. of units sold in 2006<br>No. units installed in U.S./outside U.S./list price | **CELL-DYN Ruby**<br>2006/2006/n/a<br>n/a/n/a/$185,000 | **CELL-DYN 3700**<br>1999/1999/—<br>n/a/n/a/$180,000 SL Model, $140,000 CS Model |
| **Test menu:** •Chartable<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV, •Laboratory<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso •Flags | standard menu (left) plus: MPV, RDW, RETIC #&%<br><br>#&% for bands, IG, blast, var lymph<br><br>NRBC, FWBC, NWBC, RRBC, band, IG, blast, variant lymph, RBC morph., DFLT, MCHC, LRI, URI, LURI, ATYPDEP, high/low interp. message, WBC | standard menu (left) plus: RDW, MPV, RETIC #&%, IRF<br><br>band, IG, variant lymph, blast, PCT, PDW, NRBC #&% and retic scatter profile<br><br>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**<br>**Tests not available but submitted for clearance**<br>**Tests in development**<br>**For research use only**<br>**Tests unique to analyzer** | none<br>none<br>body fluid assay<br>none<br>atypical depolarization flag | none<br>none<br>none<br>none<br>IRF |
| **Differential method(s) used**<br>**Linearity:** •WBC count ($10^9$/L)/RBC count ($10^{12}$/L)<br>•Hemoglobin (g/dL)/platelet ($10^9$/L)<br>•MCV (fL) or Hct (%)<br>**Precision:** •WBC count/RBC count<br>•Hb/platelet<br>•MCV or Hct<br>**Accuracy of automated diff. compared with manual diff.**<br>(per NCCLS H-20A), regression equation | MAPSS (Multi-Angle Polarized Scatter Separation)<br>$0.00–246 \times 10^3$/µL/$0.00–7.16 \times 10^6$/µL<br>0.00–19.9 g/dL/$11–1{,}903 \times 10^3$/µL<br>58–139 fL: (MCV)<br>2.4%/1.8%<br>1.4%/3.8%<br>0.8% (MCV)<br>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 | MAPSS (Multi-Angle Polarized Scatter Separation)<br>0–250 K/µL/0–8 M/µL<br>0–24 g/dL/0–2,000 K/µL<br>50–200 fL (MCV)<br>≤2.5%/≤1.5%<br>≤1.2%/≤5.0%<br>≤1.0% (MCV)<br>neut #&%: ≥0.95, n/a; lymph #&%: ≥0.94, n/a; mono #&%: ≥0.86, n/a; eos #&%: ≥0.84, n/a; baso #&%: ≥0.73, n/a |
| **Interfering substances:** •WBC<br><br>•RBC<br><br>•MCV or Hct<br><br>•Platelet<br><br>•Hb<br><br>**Interfering substances: differential** | fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin<br>elevated WBC, increased numbers of giant Plt, auto agglutination, in vitro hemolysis<br>MCV: elevated WBC, hyperglyc., in vitro hemolysis, increased No. of giant Plts<br>WBC fragments, in vitro hemolysis, microcytic RBC, cryofibrinogen, cryoglobulins, Plt clumping, increased No. of giant Plt<br>elevated plasma substances (triglycerides, bilirubin, in vivo hemolysis), lytic resistant RBC<br>fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin, paraproteins | NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs<br>increased No. giant Plts, autoagglutination, in vitro hemolysis<br>MCV: elevated WBC count, increased No. giant Plts, hyperglycemia, in vitro hemolysis<br>WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt clumps, increased No. giant Plts<br>increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs<br>see WBC |
| **Age- and sex-specific reference ranges**<br>**Max. CBCs per hr/max. CBCs & diffs. per hr**<br>**Recommended average frequency of calib.**<br>•Modes calibrated/parameters calibrated<br>**Frequency of blood/latex controls**<br>**Min. specimen vol. open/closed/sample dead vol. closed**<br>**Tube sampling supported**<br>**Veterinary capability**<br>**Microsample capability**<br>**Prepares microscopic slides automatically or flags**<br>problems for slide prep<br>**If auto. slidemaker available, No. installed/list price** | yes<br>up to 76/up to 76<br>6 months verification<br>open or closed/WBC, RBC, Hgb, MCV, Plt<br>per local regulatory requirements/n/a<br>150 µL/230 µL/1.2 mL<br>yes (13 × 75 mm)<br>no<br>no<br>no<br><br>>200/$125,000 | yes<br>90/90<br>6 months verification<br>open & closed/WBC, RBC, Hb, MCV, Plt<br>as per regulatory requirement/n/a<br>130 µL/355 µL/1.0 mL<br>yes (13 × 75 mm)<br>yes<br>yes<br>yes (flags only)<br><br>n/a/$125,000 |
| **Archives patient data for later comparison**<br>**Patient-specific archiving**<br>**Max. archived data accessible when system online**<br>**Memory capacity—numeric results–No. specimens**<br>**Memory capacity—histo/cytograms–No. specimens**<br>•Stored in conjunction with CBC data<br>•Histo/cytogram images & CBC data printed as 1 report<br>**Saved results can be recalled and retransmitted**<br>**Saved data can be sorted for reprocessing or report transmission**<br>**Performs delta checks**<br>**Tags and holds results for followup, confirm. testing, or rerun**<br>**Parameters for flags for holding samples are defined by**<br>**Some results can be transmitted to LIS while others held**<br>**Scattergram display: cell-specific color**<br>**Histogram display: color with threshold**<br>**Choice of desired specimen &/or result info. displayed** | yes<br>yes<br>10,000 results<br>10,000 results<br>10,000 results<br>yes<br>yes<br>yes<br>yes<br>no<br>yes<br>user or vendor<br>—<br>yes<br>yes<br>yes | yes<br>yes<br>10,000 results<br>10,000 results<br>10,000 results<br>yes<br>yes<br>yes<br>yes<br>no<br>yes<br>user or vendor<br>yes<br>yes<br>yes<br>yes |
| **LIS interface formats supported**<br>**Information transferred on LIS interface**<br><br><br>**LOINC codes transmitted with results**<br>**How labs get LOINC codes for reagent kits**<br>**Optional data mgmt. or collation system**<br>•Software features<br>**Interface avail. or planned to auto. specimen-handling system**<br>**Bar-code symbologies read on tube**<br>**Accommodates bar-code placement per NCCLS standard Auto2A** | LIS1/LIS2 CLSI<br>numeric & flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders<br>no<br>n/a<br>yes, multiple<br>enhanced QC, data archiving, data collation from multiple instruments<br>Abbott Accelerator APS (planned)<br>Codabar, codes 39 & 128, interl. 2 of 5, ISBT<br>yes | proprietary<br>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast<br><br>no<br>n/a<br>yes, multiple<br>enhanced QC, data archiving, data collation from multiple instruments<br>—<br>Codabar, codes 39 & 128, interl. 2 of 5<br>yes |
| **Time required for maintenance by lab personnel**<br>**Onboard maintenance records**<br>**Time from communication of problem to engineer on site**<br>**Onboard diagnostics/limited to software problems**<br>**Mftr. can perform diagnostics via modem** | daily: 30 sec; weekly: 5 min; monthly: 10 min<br>yes<br>territory dependent<br>yes/no<br>yes | daily: 30 sec; bi-weekly: 5 min; monthly: 10 min<br>yes<br>territory dependent<br>yes/no<br>in development |
| **Acquisition program based on cost-per-reportable result** | yes | yes |
| **Distinguishing features** | touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode | MAPSS cell-by-cell analysis provides enhanced diff.; retic with reportable IRF (immature retic. fraction); 60-species veterinary package |

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

# Hematology analyzers

| Part 3 of 11 | Abbott Hematology<br>**Deborah Archer**  deborah.archer@abbott.com<br>5440 Patrick Henry Dr.<br>Santa Clara, CA 95054<br>800-933-5535  www.abbottdiagnostics.com | Beckman Coulter Inc.<br>**Mary Beth Johnson**  mbjohnson@beckman.com<br>200 S. Kraemer Blvd.<br>Brea, CA 92822-8000<br>714-993-8438  www.beckmancoulter.com |
|---|---|---|
| **Name of instrument**<br>**First year installed in U.S./outside U.S./No. of units sold in 2006**<br>**No. units installed in U.S./outside U.S./list price** | CELL-DYN 3200<br>1997/1997/—<br>n/a/n/a/$165,000 | LH 1500 Hematology Automation Series<br>2002/2003/14<br>>50/15/varies |
| **Test menu:**<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso  •Chartable<br><br>•Laboratory<br><br>•Flags | standard menu (left) plus: RDW, MPV<br><br>band #&%, IG #&%, variant lymph #&%, blast #&%, PCT, PDW, NRBC #&%<br>band, IG, variant lymph, blast, NRBC, NWBC, RRBC, FWBC, RBC morph., high/low interp. message, LRI, URI, LURI, WBC | standard menu (left) plus: RDW, MPV, retic %&#, IRF, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial and serous fluids<br>—<br>user-definable age-, gender-, &/or location-based ref. intervals; action & critical limits; user-def. RBC morph.; user-selectable sensitivity for diff., abnormal population suspect messages |
| **FDA-cleared tests but not clinically released**<br>**Tests not available but submitted for clearance**<br>**Tests in development**<br>**For research use only**<br><br>**Tests unique to analyzer** | none<br>none<br>none<br>atypical depolarization flag outside U.S.<br><br>3-D optical RBC analysis with advanced MCV measurement | n/a<br>n/a<br>n/a<br>MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD)<br>LH 780: MAF, RSF, RDWR-SD, RDWR-CV<br>IVD: NRBC, body fluids; RUO: MSCV, WBC RPD |
| **Differential method(s) used**<br><br>**Linearity:**  •WBC count ($10^9$/L)/RBC count ($10^{12}$/L)<br>•Hemoglobin (g/dL)/platelet ($10^9$/L)<br>•MCV (fL) or Hct (%)<br>**Precision:**  •WBC count/RBC count<br>•Hb/platelet<br>•MCV or Hct<br>**Accuracy of automated diff. compared with manual diff.**<br>(per NCCLS H-20A), regression equation<br>**Interfering substances:**  •WBC<br><br>•RBC<br><br>•MCV or Hct<br><br>•Platelet<br><br>•Hb<br><br>**Interfering substances: differential** | MAPSS (Multi-Angle Polarized Scatter Separation)<br><br>0–250 K/µL/0–8 M/µL<br>0–25 g/dL/0–1,750 K/µL<br>34–172 fL (MCV)<br>≤2.7%/≤1.5%<br>≤1.0%/≤4.0%<br>≤1.0% (MCV)<br>neut #&%: ≥0.95, n/a; lymph #&%: ≥0.94, n/a; mono #&%: ≥0.86, n/a; eos #&%: ≥0.84, n/a; baso #&%: ≥0.73,  n/a<br>NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs<br>elevated WBC count, increased No. giant Plts, autoagglutination, in vitro hemolysis<br>MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased No. giant Plts<br>WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Plts<br>elevated WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs<br>see WBC | Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & AccuFlex technologies<br>0–400/0–8.0<br>0–25/0–3,000<br>50–200 (MCV)<br><1.7%/<0.8%<br><0.8%/<3.3%<br><0.8% (MCV)<br>lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a<br>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps<br>very high WBC, high conc. large Plt, autoagglutinins<br><br>very high WBC, high conc. large Plt, autoagglutinins<br><br>very small RBCs & WBC frags. may interfere<br><br>very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs<br><br>high triglycerides may affect lysing |
| **Age- and sex-specific reference ranges**<br>**Max. CBCs per hr/max. CBCs & diffs. per hr**<br>**Recommended average frequency of calib.**<br>•Modes calibrated/parameters calibrated<br>**Frequency of blood/latex controls**<br>**Min. specimen vol. open/closed/sample dead vol. closed**<br>**Tube sampling supported**<br>**Veterinary capability**<br>**Microsample capability**<br>**Prepares microscopic slides automatically or flags**<br>problems for slide prep<br>**If auto. slidemaker available, No. installed/list price** | yes<br>71/71<br>6 months verification<br>open & closed/WBC, RBC, Hb, MCV, Plt, MPV<br>as per regulatory requirement/n/a<br>150 µL/250 µL/1 mL (sample loader)<br>yes<br>no<br>yes<br>yes<br><br>n/a/$125,000 | yes<br>105 per analyzer on automation system/105 per analyzer on automation sys.<br>as dictated by your lab procedures, local or national regulations<br>primary/RBC, WBC, Hb, MCV, Plt, MPV<br>per CLIA, CAP, JCAHO, state or lab SOP/once per day<br>200 µL/300 µL, 550 µL with slidemaker/1.0 mL<br>yes<br>no<br>yes<br>yes<br><br>>850 (U.S.)/$110,000 |
| **Archives patient data for later comparison**<br>**Patient-specific archiving**<br>**Max. archived data accessible when system online**<br>**Memory capacity—numeric results–No. specimens**<br>**Memory capacity—histo/cytograms–No. specimens**<br>•Stored in conjunction with CBC data<br>•Histo/cytogram images & CBC data printed as 1 report<br>**Saved results can be recalled and retransmitted**<br>**Saved data can be sorted for reprocessing or report transmission**<br>**Performs delta checks**<br>**Tags and holds results for followup, confirm. testing, or rerun**<br>**Parameters for flags for holding samples are defined by**<br>**Some results can be transmitted to LIS while others held**<br>**Scattergram display: cell-specific color**<br>**Histogram display: color with threshold**<br>**Choice of desired specimen &/or result info. displayed** | yes<br>yes<br>10,000 results<br>10,000 results<br>10,000 results<br>yes<br>yes<br>yes<br>yes<br>no<br>yes<br>user or vendor<br>yes<br>yes<br>yes<br>yes | yes<br>yes<br>20,000 samples per instrument<br>20,000 samples per instrument<br>20,000 samples per instrument<br>yes<br>yes<br>yes<br>yes<br>yes<br>yes<br>user or vendor<br>yes<br>yes<br>yes<br>yes |
| **LIS interface formats supported**<br>**Information transferred on LIS interface**<br><br>**LOINC codes transmitted with results**<br>**How labs get LOINC codes for reagent kits**<br>**Optional data mgmt. or collation system**<br>•Software features<br><br>**Interface avail. or planned to auto. specimen-handling system**<br>**Bar-code symbologies read on tube**<br>**Accommodates bar-code placement per NCCLS standard Auto2A** | proprietary<br>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast<br>no<br>n/a<br>yes, multiple<br>enhanced QC, data archiving, data collation from multiple instruments<br><br>—<br>Codabar, codes 39 & 128, interl. 2 of 5<br>yes | RS-232<br>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast<br>no<br>contact technical support<br>yes, DL2000, Command Central<br>enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results & graphics<br>Beckman Coulter<br>Codabar, codes 39 & 128, interl. 2 of 5, NW7<br>yes |
| **Time required for maintenance by lab personnel**<br><br>**Onboard maintenance records**<br>**Time from communication of problem to engineer on site**<br>**Onboard diagnostics/limited to software problems**<br>**Mftr. can perform diagnostics via modem** | daily: 30 sec; weekly: 5 min; monthly: 10 min<br><br>yes<br>territory dependent<br>yes/no<br>in development | daily: automation system= 5 min, analyzer=0 min; weekly: automation=10 min, analyzer=0 min; monthly: automation=15 min, analyzer=2 min<br>yes<br>—<br>yes/no<br>yes |
| **Acquisition program based on cost-per-reportable result** | yes | yes |
| **Distinguishing features** | MAPSS cell-by-cell analysis provides enhanced 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 | the LH 1500 hematology automation 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 |

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

# Hematology analyzers

| Part 4 of 11 | Beckman Coulter Inc.<br>**Mary Beth Johnson**  mbjohnson@beckman.com<br>200 S. Kraemer Blvd.<br>Brea, CA 92822-8000<br>714-993-8438  www.beckmancoulter.com | Beckman Coulter Inc.<br>**Mary Beth Johnson**  mbjohnson@beckman.com<br>200 S. Kraemer Blvd.<br>Brea, CA 92822-8000<br>714-993-8438  www.beckmancoulter.com |
|---|---|---|
| **Name of instrument**<br>**First year installed in U.S./outside U.S./No. of units sold in 2006**<br>**No. units installed in U.S./outside U.S./list price** | LH 780<br>2006/2007/—<br>>60/>50/$214,500 | Coulter LH 750/LH 755<br>2001/2001/380 (U.S.)<br>>2,200/>2,000/LH 750: $195,000; LH 755: $367,500 |
| **Test menu:**<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso   •Chartable<br><br>  •Laboratory<br>  •Flags | standard menu (left) plus: RDW, RDW-SD, MPV, Retic %&#, IRF, MPV, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial and serous fluids<br>n/a<br>user-definable age-, gender-, &/or location-based ref. intervals; action and critical limits, user-def. RBC morph.; user-def. sensitivity for diff. abnormal populations, suspect and definitive messages | standard menu (left) plus: RDW, MPV, retic #&%, IRF, MPV, graded RBC morph., NRBC %&#, TNC & RBC on CSF, synovial and serous fluids<br>—<br>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**<br>**Tests not available but submitted for clearance**<br>**Tests in development**<br>**For research use only**<br><br>**Tests unique to analyzer** | n/a<br>n/a<br>n/a<br>RSF, MAF, MSCV, HLR %&#, RDWR-CV, RDWR-SD, PDW, PCT, WBC research population data (RPD)<br>IVD: NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD | n/a<br>n/a<br>n/a<br>MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD)<br>IVD: NRBC, body fluids; RUO: MSCV, WBC RPD |
| **Differential method(s) used**<br><br>**Linearity:**   •WBC count ($10^9$/L)/RBC count ($10^{12}$/L)<br>  •Hemoglobin (g/dL)/platelet ($10^9$/L)<br>  •MCV (fL) or Hct (%)<br>**Precision:**   •WBC count/RBC count<br>  •Hb/platelet<br>  •MCV or Hct<br>**Accuracy of automated diff. compared with manual diff.**<br>   (per NCCLS H-20A), regression equation<br>**Interfering substances:** •WBC<br><br>  •RBC<br>  •MCV or Hct<br>  •Platelet<br>  •Hb<br>**Interfering substances: differential** | Coulter's 3-D VCS biophysical flow cytometry with Intellikinetics, AccuGate & AccuFlex technologies<br>0–400/0–8.0<br>0–25/0–3,000<br>50–200 (MCV)<br><1.7%/<0.8%<br><0.8%/<3.3%<br><0.8% (MCV)<br>lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a<br>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps<br>very high WBC, high conc. large Plt, autoagglutinins<br>very high WBC, high conc. large Plt, autoagglutinins (MCV)<br>very small RBCs & WBC frags.<br>very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs<br>high triglycerides may affect lysing | Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & AccuFlex technologies<br>0–400/0–8.0<br>0–25/0–3,000<br>50–200 (MCV)<br><1.7%/<0.8%<br><0.8%/<3.3%<br><0.8% (MCV)<br>lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a<br>unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps<br>very high WBC, high conc. large Plt, autoagglutinins<br>MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins<br>very small RBCs & WBC frags. may interfere<br>very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs<br>high triglycerides may affect lysing |
| **Age- and sex-specific reference ranges**<br>**Max. CBCs per hr/max. CBCs & diffs. per hr**<br>**Recommended average frequency of calib.**<br>  •Modes calibrated/parameters calibrated<br>**Frequency of blood/latex controls**<br>**Min. specimen vol. open/closed/sample dead vol. closed**<br>**Tube sampling supported**<br>**Veterinary capability**<br>**Microsample capability**<br>**Prepares microscopic slides automatically or flags**<br>    problems for slide prep<br>**If auto. slidemaker available, No. installed/list price** | yes<br>105/105<br>as dictated by your lab procedures, local or national regulations<br>primary/RBC, WBC, Hgb, MCV, Plt, MPV<br>per CLIA, CAP, JCAHO, state or lab SOP/once per day<br>200 µL/300 µL (550 µL with slidemaker)/1.0 mL<br>yes<br>no<br>yes<br>yes<br><br>—/$110,000 | yes<br>105/105<br>as dictated by your lab procedures, local or national regulations<br>primary/RBC, WBC, Hb, MCV, Plt, MPV<br>per CLIA, CAP, JCAHO, state or lab SOP/once per day<br>200 µL/300 µL, 550 µL with slidemaker/1.0 mL<br>yes (multiple sizes & styles)<br>no<br>yes<br>yes, both<br><br>>850 (U.S.)/$110,000 |
| **Archives patient data for later comparison**<br>**Patient-specific archiving**<br>**Max. archived data accessible when system online**<br>**Memory capacity—numeric results–No. specimens**<br>**Memory capacity—histo/cytograms–No. specimens**<br>  •Stored in conjunction with CBC data<br>  •Histo/cytogram images & CBC data printed as 1 report<br>**Saved results can be recalled and retransmitted**<br>**Saved data can be sorted for reprocessing or report transmission**<br>**Performs delta checks**<br>**Tags and holds results for followup, confirm. testing, or rerun**<br>**Parameters for flags for holding samples are defined by**<br>**Some results can be transmitted to LIS while others held**<br>**Scattergram display: cell-specific color**<br>**Histogram display: color with threshold**<br>**Choice of desired specimen &/or result info. displayed** | yes<br>yes<br>20,000 samples<br>20,000 samples<br>20,000 samples<br>yes<br>yes<br>yes<br>yes<br>yes<br>yes<br>user or vendor<br>yes<br>yes<br>yes<br>yes | yes<br>yes<br>20,000 samples<br>20,000 samples<br>20,000 samples<br>yes<br>yes<br>yes<br>yes<br>yes<br>yes<br>user or vendor<br>yes<br>yes<br>yes<br>yes |
| **LIS interface formats supported**<br>**Information transferred on LIS interface**<br><br>**LOINC codes transmitted with results**<br>**How labs get LOINC codes for reagent kits**<br>**Optional data mgmt. or collation system**<br>  •Software features<br><br><br>**Interface avail. or planned to auto. specimen-handling system**<br>**Bar-code symbologies read on tube**<br>**Accommodates bar-code placement per NCCLS standard Auto2A** | proprietary<br>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast<br>no<br>contact technical support<br>yes, DL2000, Command Central<br>enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results & graphics, centralized result management<br>Beckman Coulter<br>Codabar, codes 39 & 128, interl. 2 of 5<br>yes | RS-232, proprietary<br>numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast<br>no<br>technical support<br>yes, DL2000, Command Central<br>enhanced QC, data archiving, common database, extensive decision rules, delta checking, patient results & graphics, centralized management of all instruments<br>Beckman Coulter<br>Codabar, codes 39 & 128, interl. 2 of 5, NW7<br>yes |
| **Time required for maintenance by lab personnel**<br><br>**Onboard maintenance records**<br>**Time from communication of problem to engineer on site**<br>**Onboard diagnostics/limited to software problems**<br>**Mftr. can perform diagnostics via modem** | daily: 0 min; weekly: 0 min; monthly: 2 min<br><br>yes<br>—<br>yes/no<br>yes | daily: 0 min; weekly: 0 min; monthly: 2 min<br><br>yes<br>—<br>yes/no<br>yes |
| **Acquisition program based on cost-per-reportable result** | yes | yes |
| **Distinguishing features** | 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 | extensive decision support; enumeration of NRBCs with every diff.; random access; automation ready; linearity for WBC and Plts; RUO: WBC RPD |

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# Hematology analyzers

| Part 5 of 11 | Beckman Coulter Inc.<br>**Mary Beth Johnson**   mbjohnson@beckman.com<br>200 S. Kraemer Blvd.<br>Brea, CA 92822-8000<br>714-993-8438   www.beckmancoulter.com | Beckman Coulter Inc.<br>**Mary Beth Johnson**   mbjohnson@beckman.com<br>200 S. Kraemer Blvd.<br>Brea, CA 92822-8000<br>714-993-8438   www.beckmancoulter.com |
|---|---|---|
| **Name of instrument** | Coulter LH 500 | Coulter HmX |
| **First year installed in U.S./outside U.S./No. of units sold in 2006** | 2003/2003/196 (U.S. only) | 1999 HmX AL, 1999 HmX CP/110 (U.S. only) |
| **No. units installed in U.S./outside U.S./list price** | >950/>1,500/$145,000 | AL: 1,175/2,100/$135,000; CP: 135/250/$120,000 |
| **Test menu:** | | |
| **All instruments have:**  •Chartable | standard menu (left) plus: retic #, retic %, MRV, IRF, RDW, MPV | standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV |
| WBC, RBC, Hb, Hct, MCV,  •Laboratory | — | — |
| MCH, MCHC, Plt, %&# neut,  •Flags | user-definable age-, gender- &/or location-based ref. intervals, action & critical limits; user-def. RBC morph.; gradient msgs. | comprehensive high/low, definitive & suspect messages |
| mono, lymph, eos, baso | | |
| **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** | PCT, PDW | PCT, PDW |
| **Tests unique to analyzer** | none | none |
| **Differential method(s) used** | Coulter's 3-D biophysical flow cytometry with AccuGate 500, Reaction Manager technologies | Coulter's 3-D VCS technology |
| **Linearity:**  •WBC count ($10^9$/L)/RBC count ($10^{12}$/L) | 0–200/0–8.0 | 0–99.9/0–7.0 |
| •Hemoglobin (g/dL)/platelet ($10^9$/L) | 0–25/0–2,000 | 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% (MCV) | <2.0% (MCV) |
| **Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation** | lymph= ±1.5 % mean diff., n/a; mono= ±1.5 % mean diff., n/a; neut= ±2.0% mean diff., n/a; eos= ±0.5 % mean diff., n/a; baso= ±0.5 % mean diff., n/a | lymph%= ±3.0%, n/a; mono%= ±2.0%, n/a; neut%= ±3.0%, n/a; eos%= ±1.0%, n/a; baso%= ±1.0%, n/a |
| **Interfering substances:**  •WBC | lyse-resistant, nucleated RBCs, frag. WBCs, agglut. WBCs, unlysed particles >35 fL, very large or agg. Plts, fibrin, cell frag., or other debris | unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt |
| •RBC | very high WBC count, many very large Plts, agglut. RBCs, RBCs <36 fL, fibrin, cell fragments, or other debris | very high WBC, high conc. of very large Plt, autoagglutinins |
| •MCV or Hct | MCV: very high WBC count, high concentration of very large Plts, agglut. RBCs, RBC fragments <36 fL, rigid RBCs | MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins |
| •Platelet | 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 & white cell frag., electronic noise, very small red cells | very small RBCs & WBC frags. may cause no fit |
| •Hb | very high WBC count, severe lipemia, heparin, lyse-resistant RBCs, turbidity such as elevated triglycerides | very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs |
| **Interfering substances: differential** | factors that affect WBC count above or high triglycerides that affect lysing, hypogran. granulocytes, agranul. granulocytes, lyse-resist. red cells, very small or multi-population lymphocytes, elevat. trigly., precipitated elev. proteins | high triglycerides may affect lysing |
| **Age- and sex-specific reference ranges** | yes | gender-specific printout |
| **Max. CBCs per hr/max. CBCs & diffs. per hr** | 75/75 | 75/75 |
| **Recommended average frequency of calib.** | as dictated by your lab procedures, local or national regulations | timing not specified |
| •Modes calibrated/parameters calibrated | primary/RBC, WBC, Hb, MCV, Plt, MPV | primary/RBC, WBC, Hb, MCV, Plt, MPV |
| **Frequency of blood/latex controls** | not specified/once per day | not specified/once per day |
| **Min. specimen vol. open/closed/sample dead vol. closed** | 125 μL/185 μL/tube dependent | 125 μL/185 μL/50 μL predilute/0.5 mL |
| **Tube sampling supported** | yes (10.25 × 75 mm or less; 13 × 75 mm or less) | 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 | yes |
| **Patient-specific archiving** | yes | yes |
| **Max. archived data accessible when system online** | 20,000 samples | 5,000 samples |
| **Memory capacity—numeric results–No. specimens** | 20,000 samples | 5,000 samples |
| **Memory capacity—histo/cytograms–No. specimens** | 20,000 samples | 5,000 samples |
| •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 | user or vendor |
| **Some results can be transmitted to LIS while others held** | yes | yes, through a selective batch process |
| **Scattergram display: cell-specific color** | yes | 4 colors/cell types |
| **Histogram display: color with threshold** | yes | colors without thresholds |
| **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, DL2000, Command Central | yes, DL2000 |
| •Software features | enhanced QC, data archiving, data collation from multiple instruments, common database, extensive decision rules, delta checking, patient results & graphics, centralized management of instruments | enhanced QC, data archiving, common database, delta checking, patient results & graphics |
| **Interface avail. or planned to auto. specimen-handling system** | — | n/a |
| **Bar-code symbologies read on tube** | Codabar, codes 39 & 128, ASTM, interl. 2 of 5, NW7 | Codabar, codes 39 & 128, interl. 2 of 5, NW7 |
| **Accommodates bar-code placement per NCCLS standard Auto2A** | yes | no |
| **Time required for maintenance by lab personnel** | none | none |
| **Onboard maintenance records** | yes | 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** | yes | no |
| **Acquisition program based on cost-per-reportable result** | yes | yes |
| **Distinguishing features** | extensive decision support, extended linearity for WBC & Plt, lowest review rate in class, small footprint, superior reliability, ProService, electronic IQAP | VCS technology; lowest review rate in class; no routine daily maintenance; triplicate counting; aperture burn circuit; sweepflow; SmartStart system; autoloader and single-sample models |

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# Hematology analyzers

| Part 6 of 11 | Beckman Coulter Inc.<br>**Kelly Colwell**  kmcolwell@beckman.com<br>200 S. Kraemer Blvd.<br>Brea, CA 92822-8000<br>714-961-4110<br>www.beckmancoulter.com | Horiba ABX Diagnostics Inc.<br>**Jim Knowles**  jknowles@us.abx.fr<br>34 Bunsen<br>Irvine, CA 92618<br>888-903-5001 ext. 553<br>www.abx.com |
|---|---|---|
| **Name of instrument** | Coulter Ac•T 5diff Family; Ac•T 5diff AL | Pentra 60C+ Hematology Analyzer |
| First year installed in U.S./outside U.S./No. of units sold in 2006 | 2001/2000; 2003/2003; open vial: 10, cap pierce: 115, autoloader: 50 | 2000/2000/52 |
| No. units installed in U.S./outside U.S./list price | 900/3,000/$43,500 cap pierce model; $38,500 open vial model; AL: 30/n/a; 300/750/$54,500 autoloader model | 340/692/$43,310 |
| **Test menu:**  •Chartable | standard menu (left) plus: RDW, MPV | standard menu (left) plus: RDW, MPV |
| All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso    •Laboratory | atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW | atyp. lymph, atyp. lymph %, LIC, LIC % |
| •Flags | complete operator selectable flagging | 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 | PCT, PDW, IMM, ATL | PCT PDW |
| Tests unique to analyzer | none | none |
| **Differential method(s) used** | AcV technology combining cytochemistry, focused flow impedance, and light absorbance prinicples of measurement | DHSS technology combining cytochemistry, focused flow impedance, & light absorbance principles of measurement |
| **Linearity:**  •WBC count ($10^9$/L)/RBC count ($10^{12}$/L) | 0.4–91.3/0.3–8.0*; AL: 0.4–120.0/0.3–8.0 | 0–120/0–8 |
| •Hemoglobin (g/dL)/platelet ($10^9$/L) | 0–22/10–1,000*; AL: 1.3–24.0/10.0–1,000 | 0.7–24/0–1,900 |
| •MCV (fL) or Hct (%) | 1.8–63.8 (Hct)* | 0.7–67 (Hct) |
| **Precision:**  •WBC count/RBC count | <2%/<2% | <2%/<2% |
| •Hb/platelet | <1%/<5% | <1%/<5% |
| •MCV or Hct | <1.0% (Hct); AL: <2.0% (Hct) | <2% (Hct) |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | not available in NCCLS H-20A format | neut% r=0.99, n/a; lymph% r=0.98, n/a;  mono% r=0.96, n/a;  eos% r=0.89, n/a; baso% r=0.54, n/a |
| Interfering substances:  •WBC | NRBCs, Plt clumps, large Plts, lyse-resistant RBCs | NRBCs, Plt clumps, lyse-resistant RBCs |
| •RBC | cold agglutinins, Plt clumps, WBC overlinearity | cold agglutinins |
| •MCV or Hct | Hct: lipemic samples, high WBC, cold aggluts | Hct: extreme leukocytosis |
| •Platelet | RBC and WBC fragments | microcytes, Plt clumps |
| •Hb | elevated WBC, lipemia | extreme lipemia/leukocytosis |
| Interfering substances: differential | lyse-resistant RBCs, NRBCs, lipemia | NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia |
| Age- and sex-specific reference ranges | yes | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 60/60; 80/80 | 60/60 |
| Recommended average frequency of calib. | not specified by time | 6 months |
| •Modes calibrated/parameters calibrated | open or closed/RBC, WBC, Hb, Hct, Plt | closed-open/WBC, RBC, Hb, Hct, Plt, MPV |
| Frequency of blood/latex controls | not specified/none | per CLIA standards/none |
| 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 | 30 µL for CBC & 53 µL for CBC + diff./30 µL for CBC & 53 µL for CBC + diff./— |
| Tube sampling supported | yes (multiple sizes) | yes (multiple sizes) |
| Veterinary capability | no | yes |
| Microsample capability | yes | yes |
| Prepares microscopic slides automatically or flags problems for slide prep | no | yes |
| If auto. slidemaker available, No. installed/list price | n/a | — |
| Archives patient data for later comparison | yes | yes |
| Patient-specific archiving | no | yes, with backup drive |
| Max. archived data accessible when system online | 10,000 samples | unlimited with backup drive |
| Memory capacity—numeric results–No. specimens | 10,000 samples | 10,000, unlimited with backup drive |
| Memory capacity—histo/cytograms–No. specimens | 10,000 samples | 10,000, unlimited with backup drive |
| •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 |
| 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 threshold | yes | yes |
| Choice of desired specimen &/or result info. displayed | yes | yes |
| LIS interface formats supported | proprietary; proprietary ASTM | ASTM 1394 & 1238, HL7, IEEE MIB |
| 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, LIS to instrument—broadcast |
| LOINC codes transmitted with results | no | yes |
| How labs get LOINC codes for reagent kits | technical support | — |
| Optional data mgmt. or collation system | yes, DL2000, Command Central | yes (MultiLink) |
| •Software features | enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delta checking, patient results & graphics available, centralized management of all instruments | enhanced QC, data archiving with Data Manager |
| Interface avail. or planned to auto. specimen-handling system | no | no |
| Bar-code symbologies read on tube | Codabar, codes 39 & 128, interl. 2 of 5, EAN 8 & 13 | 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 | none | weekly: 15 min |
| Onboard maintenance records | yes | yes |
| Time from communication of problem to engineer on site | — | 24 hrs |
| Onboard diagnostics/limited to software problems | yes/no | yes/yes |
| Mftr. can perform diagnostics via modem | no | yes, with Data Manager |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | quant. 5-part WBC diff.; aspirates only 30 µL of sample; requires small space footprint and runs quietly; AL has auto repeat based on decision rules<br>*linearity stated for Ac•T 5diff CP* | reliable 5-part WBC diff. technology—MTBF over 200 days; small footprint; small sample size of 53 µL |

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

# Hematology analyzers

| Part 7 of 11 | Horiba ABX Diagnostics Inc.<br>**Jim Knowles**  jknowles@us.abx.fr<br>**34 Bunsen**<br>**Irvine, CA 92618**<br>**888-903-5001 ext. 553**<br>www.abx.com | Horiba ABX Diagnostics Inc.<br>**Jim Knowles**  jknowles@us.abx.fr<br>**34 Bunsen**<br>**Irvine, CA 92618**<br>**888-903-5001 ext. 553**<br>www.abx.com |
|---|---|---|
| **Name of instrument**<br>First year installed in U.S./outside U.S./No. of units sold in 2006<br>No. units installed in U.S./outside U.S./list price | **Pentra XL 80**<br>2004/2003/33<br>114/310/$70,310 | **Pentra DX120**<br>2005/2004/6<br>19/400/$190,000 |
| **Test menu:**<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso  •Chartable | standard menu (left) plus: automatic dilution of overrange results<br>(WBC × 3, RBC/hgb/Plt × 2), RDW, MPV | standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV |
| •Laboratory | atyp. lymph, atyp. lymph%, LIC, LIC% | LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%,<br>RETH%, IMR%, MRU, MFI%, CRC% |
| •Flags | operator selectable flagging | — |
| **FDA-cleared tests but not clinically released** | none | double-diff. matrix pending 510 (k) |
| **Tests not available but submitted for clearance** | none | double-diff. matrix pending 510 (k) |
| **Tests in development** | none | double-diff. matrix pending 510 (k) |
| **For research use only** | PCT PDW | PCT PDW, IMG, IML, IMM |
| **Tests unique to analyzer** | automatic dilution protocol | — |
| **Differential method(s) used** | DHSS technology combining cytochemistry, focused flow impedance & light<br>absorbance | cytochemistry (chlorazol black E) and absorbance |
| **Linearity:**  •WBC count (10⁹/L)/RBC count (10¹²/L) | 0–120/0–8 | 0–150/0.5–8.1 |
| •Hemoglobin (g/dL)/platelet (10⁹/L) | 0–24/0–1,900 (>2 g/dL Hb) | 2–25/0–2,000 |
| •MCV (fL) or Hct (%) | 0–67 (Hct)/0–2,800 (<2 g/dL Hb) | 0–80 (Hct) |
| **Precision:**  •WBC count/RBC count | <2%/<2% | <2%/<2% |
| •Hb/platelet | <1%/<5% | <1%/<5% |
| •MCV or Hct | <2% (Hct) | <2% (Hct) |
| **Accuracy of automated diff. compared with manual diff.**<br>(per NCCLS H-20A), regression equation | neut% r=0.99, n/a;  lymph% r=0.98, n/a;  mono% r=0.96, n/a;  eos% r=0.89,<br>n/a; baso% r=0.54, n/a | neut% r=0.99, n/a;  lymph% r=0.98, n/a;  mono% r=0.92, n/a;  eos% r=0.97,<br>n/a; baso% r=0.71, n/a |
| **Interfering substances:**  •WBC | NRBCs, Plt clumps, lyse-resistant RBCs | NRBCs, Plt clumps, lyse-resistant RBCs |
| •RBC | cold agglutinins | cold agglutinins |
| •MCV or Hct | Hct: extreme leukocytosis | Hct: extreme leukocytosis |
| •Platelet | microcytes, Plt clumps | microcytes, Plt clumps |
| •Hb | extreme lipemia, leukocytosis | extreme lipemia, leukocytosis |
| **Interfering substances: differential** | NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia | NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia |
| **Age- and sex-specific reference ranges** | yes | yes |
| **Max. CBCs per hr/max. CBCs & diffs. per hr** | 80/80 | 120/120 |
| **Recommended average frequency of calib.** | 6 months | 6 months |
| •Modes calibrated/parameters calibrated | open, closed/WBC, RBC, Hb, Hct, Plt, MPV | open, closed/WBC, RBC, Hb, Hct, Plt, MPV |
| **Frequency of blood/latex controls** | per CLIA standards/none | per CLIA standards/none |
| **Min. specimen vol. open/closed/sample dead vol. closed** | 30 µL for CBC/53 µL for CBC + diff./0.5 mL | 130 µL/200 µL/1 mL |
| **Tube sampling supported** | yes (autoloader 13 × 75; closed tube 16 sizes + micro) | yes |
| **Veterinary capability** | yes | yes |
| **Microsample capability** | yes | yes, open mode |
| **Prepares microscopic slides automatically or flags<br>problems for slide prep** | yes | yes |
| **If auto. slidemaker available, No. installed/list price** | —/— | —/— |
| **Archives patient data for later comparison** | yes | yes |
| **Patient-specific archiving** | yes, with MultiLink Data Manager | yes |
| **Max. archived data accessible when system online** | MultiLink Data Manager; 10,000 instrument only | unlimited Data Manager; 10,000 instrument only |
| **Memory capacity—numeric results–No. specimens** | MultiLink Data Manager; 10,000 instrument only | unlimited Data Manager |
| **Memory capacity—histo/cytograms–No. specimens** | MultiLink Data Manager | unlimited 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 | user |
| **Some results can be transmitted to LIS while others held** | yes | — |
| **Scattergram display: cell-specific color** | yes | yes |
| **Histogram display: color with threshold** | yes | yes |
| **Choice of desired specimen &/or result info. displayed** | — | yes |
| **LIS interface formats supported** | proprietary, ASTM 1394 & 1238, HL7, IEEE MIB | proprietary, ASTM 1394 & 1238, HL7, IEEE MIB |
| **Information transferred on LIS interface** | numeric & flag results, histograms & scatterplots, instrument to LIS;<br>patient demographics, orders, LIS to instrument— broadcast | numeric & flag results, histograms & scatterplots, instrument to LIS;<br>patient demographics, orders, LIS to instrument— broadcast |
| **LOINC codes transmitted with results** | n/a | n/a |
| **How labs get LOINC codes for reagent kits** | n/a | n/a |
| **Optional data mgmt. or collation system** | yes (MultiLink) | yes (MultiLink) |
| •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** | yes | yes |
| **Bar-code symbologies read on tube** | Codabar, codes 39 & 128, ASTM, 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** | weekly: 15 min | weekly: 15 min |
| **Onboard maintenance records** | yes | yes |
| **Time from communication of problem to engineer on site** | 24 hrs | — |
| **Onboard diagnostics/limited to software problems** | no/yes | no/yes |
| **Mftr. can perform diagnostics via modem** | yes | yes |
| **Acquisition program based on cost-per-reportable result** | yes | yes |
| **Distinguishing features** | compact 5-part differential instrument with autoloader and autodilution<br>capability, autorerun feature, autovalidation | high-throughput cell counter with integrated reticulocyte methodology and<br>slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing,<br>autovalidation |

# Hematology analyzers

| Part 8 of 11 | | Siemens Medical Solutions Diagnostics<br>Ron Hebert<br>511 Benedict Ave.<br>Tarrytown, NY 10591<br>800-255-3232  www.siemens.com/diagnostics | Siemens Medical Solutions Diagnostics<br>Ron Hebert<br>511 Benedict Ave.<br>Tarrytown, NY 10591<br>800-255-3232  www.siemens.com/diagnostics |
|---|---|---|---|
| **Name of instrument**<br>**First year installed in U.S./outside U.S./No. of units sold in 2006**<br>**No. units installed in U.S./outside U.S./list price** | | Advia 120 Hematology System<br>1998/1998/—<br>>750/3,500/$169,000–$189,000 | Advia 2120 Hematology System<br>2004/2004/—<br>>200/>900/$225,000 |
| **Test menu:**<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso | •Chartable<br><br><br>•Laboratory<br><br><br>•Flags | standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellular Hgb<br>%: hypo, hyper, macro, micro; calc. Hb, MPXI; %: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost count<br>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 | standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHr, CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono<br>% hypo, hyper, macro, micro; MPXI, %: blast, PMN, MN, large Plt count, RBC fragment count; RBC ghost count, NRBC<br>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 |
| **FDA-cleared tests but not clinically released** | | none | none |
| **Tests not available but submitted for clearance** | | none | none |
| **Tests in development** | | IRF, MPC, MPM | MPC, MPM |
| **For research use only** | | CSF, eos | IRF, CSF, eos |
| **Tests unique to analyzer** | | CHCM, HDW, CHr, CHCMr, MPC, MPM; CSF: WBC RBC, MN, PMN, neut, lymph, mono | CHCM, HDW, CHr, CHCMr, cellular Hgb, MPC, MPM; CSF: WBC, RBC, PMN, MN, neut, lymph, mono |
| **Differential method(s) used** | | perox–peroxidase cytochem. staining with light scatter & absorption; baso–cytochem. stripping with 2-angle laser light scatter | peroxidase WBC—peroxidase cytochem. staining w/ light scatter & absorption; baso—cytochem. stripping w/ 2-angle laser light scatter |
| **Linearity:** | •WBC count ($10^9$/L)/RBC count ($10^{12}$/L)<br>•Hemoglobin (g/dL)/platelet ($10^9$/L)<br>•MCV (fL) or Hct (%) | 0.02–400/0–7.0; CSF WBC 0–5,000/µL; CSF RBC 0–1,500/µL<br>0–22.5 /5–3,500<br>30–180 (MCV) | 0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500<br>0–22.5/5–3,500<br>30–180 (MCV) |
| **Precision:** | •WBC count/RBC count<br>•Hb/platelet<br>•MCV or Hct | 2.7%/1.2%<br>0.93%/2.93%<br>0.78% (MCV) | 2.7%/1.2%<br>0.93%/2.93%<br>0.78% (MCV) |
| **Accuracy of automated diff. compared with manual diff.**<br>    (per NCCLS H-20A), regression equation | | neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6 | neut% r=0.997, y=1.02x–0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x–0.3;  eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92x+0.6 |
| **Interfering substances:** | •WBC<br>•RBC<br>•MCV or Hct<br>•Platelet<br>•Hb | incomplete RBC lysis (perox only)<br>cold agglutinins, extreme sickle cell<br>none<br>none<br>high WBC, lip., extremely high bili., interfere with cyanmethb. only, none with direct cellular Hb (CHCM) | incomplete RBC lysis (peroxidase only)<br>cold agglutinins, extreme sickle cell<br>none<br>none<br>extreme lipemia, high WBC, extreme high bili. interference w/ colorimetric Hb only, none with cellular Hb |
| **Interfering substances: differential** | | incomplete lysis of RBCs, complete myeloperox. deficiency | incomplete RBC lysis, complete myeloperox. deficiency |
| **Age- and sex-specific reference ranges** | | yes | yes |
| **Max. CBCs per hr/max. CBCs & diffs. per hr** | | 120/120 | 120/120 |
| **Recommended average frequency of calib.** | | 6 months | 6 months |
| | •Modes calibrated/parameters calibrated | open, closed, autosampler/all measured parameters | autosampler, closed, open/all measured parameters |
| **Frequency of blood/latex controls** | | once per shift/not required | once per shift/not required |
| **Min. specimen vol. open/closed/sample dead vol. closed** | | 157 µL/157 µL/<300 µL (tube size dependent) | 175 µL/175 µL/<300 (tube size dependent) |
| **Tube sampling supported** | | yes (2, 3, 5, 7 mL—all sizes–open tube) | yes (2, 3, 5, 7 mL—all sizes open) |
| **Veterinary capability** | | yes | yes |
| **Microsample capability** | | yes | yes |
| **Prepares microscopic slides automatically or flags**<br>    problems for slide prep | | yes | if integrated to Advia Autoslide |
| **If auto. slidemaker available, No. installed/list price** | | — | Advia Autoslide, n/a/$98,000 |
| **Archives patient data for later comparison** | | yes | yes |
| **Patient-specific archiving** | | no | no |
| **Max. archived data accessible when system online** | | 10,000 samples | 10,000 |
| **Memory capacity—numeric results–No. specimens** | | 10,000 samples | 10,000 |
| **Memory capacity—histo/cytograms–No. specimens** | | 10,000 samples | 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 threshold** | | yes | yes |
| **Choice of desired specimen &/or result info. displayed** | | yes | yes |
| **LIS interface formats supported** | | proprietary (Spec 79) | proprietary |
| **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, patient orders, LIS to instrument— broadcast; host query for patient demographics and orders (when bar code is read, host is queried for orders) |
| **LOINC codes transmitted with results** | | no | no |
| **How labs get LOINC codes for reagent kits** | | online documentation | online documentation |
| **Optional data mgmt. or collation system** | | yes (CentraLink) | yes (CentraLink) |
| | •Software features | enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated diff. pad, remote diagnostics, remote workstations | enhanced QC, data archiving, data collation from multiple instruments, autovalidation, integrated diff. pad, remote diagnostics, remote workstations |
| **Interface avail. or planned to auto. specimen-handling system** | | LabCell (Siemens) | LabCell (Siemens) |
| **Bar-code symbologies read on tube** | | Codabar, codes 39 & 128, ASTM, interl. 2 of 5 | Codabar, codes 39 & 128, interl. 2 of 5 |
| **Accommodates bar-code placement per NCCLS standard Auto2A** | | yes | — |
| **Time required for maintenance by lab personnel** | | daily: 10 min; weekly: 15 min; monthly: 15 min | daily: 0 min; weekly: 15 min; monthly: 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** | | 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 | 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 |

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

# Hematology analyzers

| Part 9 of 11 | | Sysmex America Inc.<br>Audrey Woodbeck<br>1 Nelson C. White Pkwy.<br>Mundelein, IL 60060<br>800-379-7639<br>www.sysmex.com/usa | Sysmex America Inc.<br>Audrey Woodbeck<br>1 Nelson C. White Pkwy.<br>Mundelein, IL 60060<br>800-379-7639<br>www.sysmex.com/usa |
|---|---|---|---|
| Name of instrument | | Sysmex XE-2100 | Sysmex XE-2100D |
| First year installed in U.S./outside U.S./No. of units sold in 2006 | | 2000/—/200 | 2004/2004/12 |
| No. units installed in U.S./outside U.S./list price | | 1,050/3,700/$225,000 | 12/—/$200,000 |
| Test menu: | •Chartable | standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV, IG%, IG#, RET-He, IPF | standard menu (left) plus: RDW-SD, RDW-CV |
| All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso | •Laboratory | none | none |
| | •Flags | Plt clumps, RBC agglut, turbidity, WBC ABN scattergram, RBC ABN distrib., Plt ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph./blast., ret. ABN scattergram | Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blast, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity |
| FDA-cleared tests but not clinically released | | none | n/a |
| Tests not available but submitted for clearance | | none | n/a |
| Tests in development | | — | n/a |
| For research use only | | P-LCR, PCT, PDW | P-LCR, PCT, PDW |
| Tests unique to analyzer | | HPC#, IG%, IG#, RET He, IPF | Optional: IG% & IG# |
| Differential method(s) used | | fluorescent flow cytometry, RF/DC detecting method | fluorescent flow cytometry |
| Linearity: | •WBC count ($10^9$/L)/RBC count ($10^{12}$/L) | 0–440/0–8 | 0–440/0–8 |
| | •Hemoglobin (g/dL)/platelet ($10^9$/L) | 0–25/0–5,000 | 0–25/0–5,000 |
| | •MCV (fL) or Hct (%) | 0–75 (Hct) | 0–75 (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 | <1.5% (Hct) | ≤1.5% (Hct) |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | | neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922 | neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922 |
| Interfering substances: | •WBC | cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs | cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs |
| | •RBC | cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis | cold agglut., severe microcytosis, frag. RBCs, leukocytosis |
| | •MCV or Hct | Hct: cold agglutinins, leukocytosis, ABN red cell fragility, spherocytosis | Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis |
| | •Platelet | pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts | pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts |
| | •Hb | lipemia, ABN proteins in blood plasma, severe leukocytosis | lipemia, ABN proteins, leukocytosis |
| 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 slide prep | | yes with Alpha or HST upgrade | yes, with Alpha or HST upgrade |
| If auto. slidemaker available, No. installed/list price | | >1,000/price depends on configuration | >1,000/— |
| 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 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 | 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 &/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, patient demographics, orders | numeric & flag results, histograms & 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, proprietary | yes, proprietary |
| •Software features | | enhanced QC, data archiving, data collation from multiple instruments, multiple sites | enhanced QC, data archiving, data collation from multiple instruments, multiple sites |
| Interface avail. or planned to auto. specimen-handling system | | Roche, Labotix, IDS, A&T, Thermo | Roche, Labotix, A&T, IDS, Thermo |
| Bar-code symbologies read on tube | | Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13 | Codabar, codes 39 & 128, ASTM, interl. 2 of 5, ITF, NW7, EAN 8 & 13 |
| Accommodates bar-code placement per NCCLS 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 QC; remote diagnostics, body fluid analysis; platelet linearity to 5 million, hematocrit non-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. | 150 CBC/hr; platelet linearity—5 million, hematocrit extended to 75%; standardized technology, reagents, controls and operations |

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

# Hematology analyzers

| Part 10 of 11 | Sysmex America Inc.<br>Nilam Patel<br>1 Nelson C. White Pkwy.<br>Mundelein, IL 60060<br>800-379-7639<br>www.sysmex.com/usa | Sysmex America Inc.<br>Margaret Triola<br>1 Nelson C. White Pkwy.<br>Mundelein, IL 60060<br>800-379-7639<br>www.sysmex.com/usa |
|---|---|---|
| **Name of instrument** | **Sysmex XE-Alpha N/HST-N** | **Sysmex XT-2000i** |
| First year installed in U.S./outside U.S./No. of units sold in 2006 | 2000/—/50 | 2002/2001/150 |
| No. units installed in U.S./outside U.S./list price | >1,000 worldwide/$360,000–$1,000,000 | 550/3,500/$145,000 |
| **Test menu:** •Chartable<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso | standard menu (left) plus: RDW-SE, RDW-CV, IG%, IG#, NRBG%, NRBC#, retic%&#, IRF, Plt-O (fluorescent optical Plt), HPC#, MPV; RET-He (Reticulocyte Hgb Equivalent), IPF (immature platelet fraction), HPC (hematopoietic progenitor cells) | standard menu (left) plus: retic %&#, IRF, Plt-O, MPV, RDW-SD, RDW-CV |
| •Laboratory | none | none |
| •Flags | user defined, all inclusive | user defined, all inclusive |
| FDA-cleared tests but not clinically released | none | — |
| Tests not available but submitted for clearance | none | — |
| Tests in development | — | immature gran. %&# |
| For research use only | P-LCR, PCT, PDW | IG%&# |
| Tests unique to analyzer | NRBC, HPC#, IG%, IG# | Plt-O |
| **Differential method(s) used** | fluorescent flow cytometry, RF/DC detecting method | fluorescent flow cytometry |
| **Linearity:** •WBC count ($10^9$/L)/RBC count ($10^{12}$/L) | 0–440/0–8 | 0–310/0–8 |
| •Hemoglobin (g/dL)/platelet ($10^9$/L) | 0–25/0–5,000 | 0–25/0–5,000 |
| •MCV (fL) or Hct (%) | 0–75 (Hct) | 0–60 (Hct) |
| **Precision:** •WBC count/RBC count | <3%/<1.5% | ≤3.0%/≤1.5% |
| •Hb/platelet | <1.0%/<4.0% | ≤1.5%/≤4.0% |
| •MCV or Hct | <1.0% (Hct) | ≤1.5% (Hct) |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922 | neut% r=0.95, y=0.95x+3.38; lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24 |
| **Interfering substances:** •WBC | cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs | cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs |
| •RBC | cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis | cold agglut., severe microcytosis, frag. RBCs, leukocytosis |
| •MCV or Hct | Hct: cold agglut., leukocytosis, ABN red cell fragility, spherocytosis | Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/µL) |
| •Platelet | pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts | pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts |
| •Hb | lipemia, ABN proteins in blood plasma, severe leukocytosis | 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 per analyzer on automation system | 80/80 |
| 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/— |
| Frequency of blood/latex controls | per CLIA requirements/none | per CLIA requirements/none |
| Min. specimen vol. open/closed/sample dead vol. closed | 130 µL/200 µL/1 mL | 85 µL/150 µL/1 mL |
| Tube sampling supported | yes | yes |
| Veterinary capability | no | yes, XT-V product |
| Microsample capability | yes | yes |
| Prepares microscopic slides automatically or flags problems for slide prep | yes | no |
| 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 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 | 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 &/or result info. displayed | yes | yes |
| **LIS interface formats supported** | RS-232C/TCP IP | RS-232/TCP-IP, ASTM |
| Information transferred on LIS interface | numeric & flag results, histograms & scatterplots, patient demographics, orders | numeric & flag results, histograms & 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, proprietary | yes, proprietary |
| •Software features | enhanced QC, data archiving, data collation from multiple instruments, multiple sites | enhanced QC, data archiving, data collation from multiple instruments |
| Interface avail. or planned to auto. specimen-handling system | Roche, Labotix, IDS, A&T | n/a |
| Bar-code symbologies read on tube | Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13 | Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13 |
| Accommodates bar-code placement per NCCLS 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** | high throughput, flexible, scalable 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 | high throughput, remote diagnostics; online QC; random access; fluorescent optical platelets; discrete testing; reagent monitoring; customized chartable report formats; XT-V unit for use in toxicology & research and veterinary reference labs; body fluids now FDA cleared, standardized technology, reagents, controls and operations with other X-Series analyzers |

# Hematology analyzers

| Part 11 of 11 | Sysmex America Inc.<br>Margaret Triola<br>1 Nelson C. White Pkwy.<br>Mundelein, IL 60060<br>800-379-7639<br>www.sysmex.com/usa | Sysmex America Inc.<br>Margaret Triola<br>1 Nelson C. White Pkwy.<br>Mundelein, IL 60060<br>800-379-7639<br>www.sysmex.com/usa |
|---|---|---|
| **Name of instrument** | Sysmex XT-1800i | XS-1000i and XS-1000i AutoLoader (20 sample autoloader option) |
| First year installed in U.S./outside U.S./No. of units sold in 2006 | 2002/—/150 | 2005/2006/— |
| No. units installed in U.S./outside U.S./list price | 760/4,100/$125,000 | 2781/200/$85,000 (XS-1000i) $95,000 (AutoLoader) |
| **Test menu:**   •Chartable<br>All instruments have:<br>WBC, RBC, Hb, Hct, MCV,<br>MCH, MCHC, Plt, %&# neut,<br>mono, lymph, eos, baso | standard menu (left) plus: MPV, RDW-SD, RDW-CV | standard menu (left) plus: MPV, RDW-SD, RDW-CV |
|   •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, 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 | body fluids | none |
| Tests not available but submitted for clearance | none | none |
| Tests in development | immature gran. %&# | none |
| For research use only | IG%&# | research screen |
| Tests unique to analyzer | — | — |
| **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 | 0–400/0-8 |
|   •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 | ≤3.0%/≤1.5% | —/— |
|   •Hb/platelet | ≤1.5%/≤4.0% | —/— |
|   •MCV or Hct | ≤1.5% (Hct) | — |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | neut% r=0.95, y=0.95x+3.38;  lymph% r=0.96, y=0.85x+1.67; mono% r=0.90, y=11.37x+1.89; eos% r=0.94, y=0.87x+0.04; baso% r=0.76, y=0.48x+0.24 | neut% r=0.96, y=0.9074x+3.8948; lymph% r=0.97, y=0.9017x+2.4817; mono% r=0.78, y=0.8626x+3.5938; eos% r=0.94, y=0.9076x+0.3651; baso% r=0.29, y-0.1538x+0.298 |
| **Interfering substances:**   •WBC | 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 | cold agglut., severe microcytosis, frag. RBCs, leukocytosis |
|   •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 | lipemia, ABN proteins, leukocytosis |
| 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 | 60/60 |
| Recommended average frequency of calib. | once per year by FSR | once per year |
|   •Modes calibrated/parameters calibrated | open, closed, capillary/— | closed & capillary/— |
| Frequency of blood/latex controls | per CLIA requirements/none | per CLIA requirements/none |
| Min. specimen vol. open/closed/sample dead vol. closed | 85 μL/150 μL/1 mL | 20 μL/20 μL/1.0 mL |
| Tube sampling supported | yes | yes (up to 85 mm height) |
| Veterinary capability | yes, XT-V product | 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 | yes |
| **Patient-specific archiving** | yes | yes |
| **Max. archived data accessible when system online** | 10,000 samples | 10,000 specimens |
| **Memory capacity—numeric results–No. specimens** | 10,000 samples | 10,000 specimens |
| **Memory capacity—histo/cytograms–No. specimens** | 10,000 samples | 10,000 specimens |
|   •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 threshold** | yes | yes |
| **Choice of desired specimen &/or result info. displayed** | yes | yes |
| **LIS interface formats supported** | RS-232C/TCP-IP, ASTM | proprietary, ASTM 1394, TCP-IP |
| **Information transferred on LIS interface** | numeric & flag results, histograms & scatterplots, patient demographics, orders | numeric & flag results, histograms & 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, proprietary | yes, Molis WAM-proprietary |
|   •Software features | enhanced QC, data archiving, data collation from multiple instruments, multiple sites | enhanced QC, data archiving, data collation from multiple instruments, multiple sites |
| **Interface avail. or planned to auto. specimen-handling system** | n/a | — |
| **Bar-code symbologies read on tube** | Codabar, codes 39 & 128, interl. 2 of 5, ITF, NW7, EAN 8 & 13 | Codabar, codes 39 & 128, ASTM, interl. 2 of 5, NW7, EAN 8 & 13, ITF |
| **Accommodates bar-code placement per NCCLS standard Auto2A** | yes | yes |
| **Time required for maintenance by lab personnel** | daily: <3 min. | daily: 3 min; weekly: none; monthly: 9 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** | remote diagnostics; online QC; random access; discrete testing; reagent monitoring; chartable report formats; XT-V for use in toxicology, research and veterinary reference labs; unique specimen-gating SW is FDA Part II compliant; body fluids now FDA cleared; standardized technology, reagents, controls and operations with other X-Series analyzers | standardized technology, reagents, controls and operations to other X-Series analyzers; small sample volume requirements for CBC + 5 part diff. |

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