



New QC, parameters, and automation for hematology analyzers

Anne Ford

As Mary Beth Johnson, Beckman Coulter marketing manager, rediscovered on a trip to Best Buy the other day, the breakneck pace at which today's technology evolves can sometimes leave consumers in the dust. When the salesman she spoke with there found out that her television was a whopping four years old, "he just looked at me like, 'Gosh, no one has *these* things anymore,'" she says. "He was telling me, 'Oh, this is so out of

date.' All I could say was, 'What?'" At Beckman Coulter, she says, "We don't want that to happen to our customers."

That's why the company is planning to make some of the functionality of its high-volume hematology analyzer, the recently introduced LH 780, available in the form of a software upgrade for customers who already own Beckman Coulter's LH 750 instrument. "We have about 2,000 LH 750s out there, which is a substantial number," Johnson says. "Of course there's

differentiation between the two systems. But some of the things, like the QC package, will be added back to the 750. So we're taking care of our current customers as well. That makes you feel really good."

Along with a score of other products from several different vendors, the LH 780 and LH 750 appear in this month's instrumentation survey, which focuses on hematology analyzers for high-volume laboratories. The five manufacturers represented offer an array

of new instruments and features that reflect Sysmex senior marketing manager Nilam Patel's statement: "We're always looking at what the market needs are and how we can take hematology to the next level."

One of the latest developments from Sysmex: the RET-He, or reticulocyte hemoglobin equivalent, parameter, which is being made available on the company's XE series of analyzers. "We're finding in the studies that we've done that RET-He is a more sensitive indicator of functional iron deficiency anemia, more so than some of the biochemical markers that are traditionally used," says Sysmex diagnostics market manager Barbara Connell. "We've got some folks who are beginning to use the parameter," Patel adds. "The nice thing about it is that this parameter is available to current customers with just an upgrade to the software." And with no additional sample draw required, "it's very convenient to get that parameter from the same lavender-top tube."

In the last several months, Sysmex customers have been able to access another new parameter as well—IPF, or immature platelet fraction. "We think this really has broad application," Connell says. "We feel that IPF may help in treating a patient that has thrombocytopenia." Without this parameter, she says, laboratories have to perform a reticulated platelet count, a flow cytometry procedure that many labs must send to a reference laboratory for completion. "If they do have a flow lab and they want to start using this procedure, they're looking at a more complicated procedure—something that typically needs a dedicated technologist. Whereas with IPF, it's available 24 hours a day, seven days a week, on their routine hematology analyzer," Connell says.

As readers of the 2005 CAP TODAY hematology instrumentation survey may recall, Sysmex has been working with Bio-Rad Laboratories to make the latter's Variant II Turbo hemoglobin system available on Sysmex's HST-N hematology automation line. Patel reports that her company plans to launch the product in the first quarter of 2007. "The purpose of this, again, is to give the advantage to labs to draw just that one single purple top and put it on the automation line," she says.

In addition to providing a software upgrade to owners of the LH 750, Beckman Coulter is also touting the features of its new LH 780, which this year's AACC attendees previewed and which the company

continued on page 14



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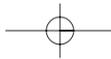
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Analyzers

continued from page 12

plans to begin shipping this month. "The LH 780 really focuses on two primary areas," Johnson says. "We're looking at enhanced functionality as well as advanced technology with research parameters." Regarding the latter, she says, "Our customers can use this information to gain further insight on changes at the cellular level for the different types of white blood cells as well as insight on the red blood cells and platelets. It's really cool."

Other features of the LH 780: a new RDW-SD parameter, shown to help differentiate anemias; a user-friendly interface; and the XM quality control package, which offers exponentially weighted moving average, or EWMA, of CBC, five-part differential, nucleated red blood cell count, and reticulocyte parameters. Extended QC rules for measuring total air imprecision and bias are also available. A companion instrument, the LH 785, adds Beckman Coulter's LH SlideMaker and SlideStainer to the LH 780.

The buzz at Bayer these days focuses on a forthcoming hematology automation solution that will feature Bayer's Advia 2120 and Advia AutoSlide hooked onto the company's Advia LabCell system. Ron Hebert, senior product manager worldwide for hematology, says, "We're also working on body fluids—the ability to have a complete body fluid panel on the Advia 2120, which would be the plural peritoneal and dialysate fluids." Hebert continues, "We're very unique in the fact that we offer true, practical automation, where we can truly automate all the manual procedures that a hematology laboratory does on a daily basis without the need for large track-based systems or reflexive testing or special stains. We're able to do it and get accurate results on the first pass."

In the future, Hebert says, the data that hematology analyzers provide will fuel automated diagnosis of patient samples. "Bayer has the ability to offer a 'neural net' of information," he says. "This has been shown to offer great potential as a practical tool for medical staff to offer an automated differential diagnosis, which can lead to earlier diagnosis and more effective treatment for patients. We look at that as true information technology."

CAP TODAY's survey of hematology analyzers for high-volume laboratories includes systems from the aforementioned manufacturers and from Abbott Hematology and Horiba ABX Diagnostics. Vendors supplied the information listed. Readers interested in a particular analyzer should confirm it has the stated features and capabilities. □

Anne Ford is a writer in Chicago.

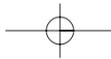
High-volume hematology analyzers

| | |
|---|--|
| Part 1 of 12 <i>See related article, page 12</i> | Abbott Hematology Deborah Archer 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com |
| Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2005 No. units installed in U.S./outside U.S./list price | CELL-DYN Sapphire 2005/2005/— n/a/n/a/\$250,000 |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, % neut, mono, lymph, eos, baso FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer | Chartable Laboratory Flags standard menu (left) plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8 — band, IG, blast, variant lymph, nvWBC, rstRBC, IR, Plt clmp, ASYM, FP, CD61 agg., clot detected during aspiration, short sample none none body fluid assay, optical RBC morphology none CD61 for Plts, WVF, CD3/4, CD3/8 (immuno T-cell) |
| Differential method(s) used Linearity: Precision: Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation Interfering substances: | optical scatter & 3-color fluorescence 0.4–250.0 × 10 ³ µL / 0.0–7.50 × 10 ⁶ µL 7–24.8 g/dL (cyanide free)/11.0–2000.0 × 10 ³ µL 37.0–179 fL (MCV) ≤2.7%/≤1.5% ≤1.0%/≤4.0% ≤1.0% (MCV) neut% r=0.942 slope 0.947 y=0.446; lym% r=0.936 slope=0.943 y=2.811; mono% r=0.623 slope=1.057 y=0.851; eos% r=0.446 slope=1.024 y=0.288; baso% r=0.232 slope=0.257 y=0.350 Plt clumps, neut aggregates, Hb C crystals, lyse-resist. RBCs, cryoglob., cryofibr., frag. WBC, nRBC autoagg., cold agg., elevated WBC, giant Plts, hemolysis, sm WBC MCV: autoagg., cold agg., elevated WBC, giant Plt, hemolysis, hyperglycemic Plt satellitism, RBC frag, WBC frag, microcytic RBC auto & cold agg, cryoglob., cryofibrin., giant Plt, micro RBC, Plt clumps lipids>700 mg/dL, WBCs>250 × 10 ⁹ /L, bilirubin>33 mg/dL, Hb crystals see WBC |
| Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If auto. slidemaker available, No. installed/list price | yes 106/106 6 months verification open-closed single procedure/WBC, RBC, Hb, Plt, MPV per regulatory requirement/n/a 117 µL/117 mL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes yes (11.5–13 × 65–75 mm, 10.25 × 64 mm, 9 × 66 mm [Sarstedt Monovette]) no yes yes (flags only) n/a/\$125,000 |
| Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens Stored in conjunction with CBC data Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by user or vendor Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen &/or result info. displayed | yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes yes user or vendor yes yes yes |
| LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system Software features Interface avail. or planned to auto. specimen-handling system Accelerator APS Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A | ASTM 1394 numeric & flag results, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics & orders no n/a yes, Abbott Accelerator DM enhanced QC, data archiving, data collation from multiple instruments, remote viewing Accelerator APS Codabar, codes 39 & 128, interl. 2 of 5 yes |
| Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mfr. can perform diagnostics via modem | daily: 30 sec; weekly: 10 min; monthly: 5 min yes — yes/no no |
| Acquisition program based on cost-per-reportable result | yes |
| Distinguishing features | 4 optical and 3 fluorescent detectors providing Multiple Scatterplot Analysis; 2-D optical platelets that avoid interferences; fluorescent analysis of reticulocytes, nRBCs, and 3-color monoclonal analysis on a routine hematology analyzer |

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

Survey editor: Raymond D. Aller, MD



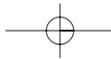


High-volume hematology analyzers

| Part 2 of 12 See related article, page 12 | Abbott Hematology Jeff Kolberg jeff.kolberg@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com | Abbott Hematology Jeff Kolberg jeff.kolberg@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com |
|--|--|--|
| Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2005 No. units installed in U.S./outside U.S./list price | CELL-DYN Ruby 2006/2006/n/a n/a/n/a/\$185,000 | CELL-DYN 3700 1999/1999/— n/a/n/a/\$180,000 SL Model, \$140,000 CS Model |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | <ul style="list-style-type: none"> •Chartable •Laboratory •Flags standard menu (left) plus: MPV, RDW, RETIC #&#% #&#% for bands, IG, blast, var lymph — | standard menu (left) plus: RDW, MPV, retic #&#%, IRF band, IG, variant lymph, blast, PCT, PDW, NRBC #&#% and retic scatter profile 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 Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer | none none body fluid assay none atypical depolarization flag | none none none none IRF |
| Differential method(s) used Linearity: •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation Interfering substances: •WBC •RBC •MCV or Hct •Platelet •Hb Interfering substances: differential | MAPSS (Multi-Angle Polarized Scatter Separation) 0.00–246 × 10 ³ /μL/0.00–7.16 × 10 ⁶ /μL 0.00–19.9 g/dL/0.00–1,903 × 10 ³ /μL 0.00–139 fL: (MCV) 2.4%/1.8% 1.4%/3.8% 0.8% (MCV) neu% r=0.983, slope=0.97, y=-1.98; lymph r=0.921, slope=0.95, y=0.94; mono r=0.711, slope=1.10, y=1.93; eos r=0.952, slope=1.04, y=0.01; baso r=0.146, slope=0.18, y=1.22 fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin elevated WBC, increased numbers of giant Plt, auto agglutination, in vitro hemolysis MCV: elevated WBC, hyperglyc., in vitro hemolysis, increased No. of giant Pits WBC fragments, in vitro hemolysis, microcytic RBC, cryofibrinogen, cryoglobulins, Plt clumping, increased No. of giant Plt elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo hemolysis, lytic resistant RBC) fragile WBC, neutrophil aggregates, lytic-resistant RBC, NRBC, Plt clumps, cryofibrinogen, cryoglobulin, paraproteins | MAPSS (Multi-Angle Polarized Scatter Separation) 0–250/0–8 0–24/0–2,000 50–200 (MCV) ≤2.5%/≤1.5% ≤1.2%/≤5.0% ≤1.0% (MCV) 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 NRBCs (WIC only), lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrino- gen, fragile WBCs increased No. giant Pits, autoagglutination, in vitro hemolysis MCV: elevated WBC count, increased No. giant Pits, hyperglycemia, in vitro hemolysis WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulin, Plt clumps, increased No. giant Pits increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs see WBC |
| Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. •Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If auto. slidemaker available, No. installed/list price | yes up to 76 per hour/up to 76 per hour 6 months verification open or closed/WBC, RBC, Hgb, MCV, Plt per local regulatory requirements/n/a 150 μL/230 μL/1.2 mL yes (13 × 75 mm) no no no >200/\$125,000 | yes 90/90 6 months verification open & closed/WBC, RBC, Hb, MCV, Plt as per regulatory requirement/n/a 130 μL/355 μL/1.0 mL yes (13x75 mm) yes yes yes (flags only) n/a/\$125,000 |
| Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens •Stored in conjunction with CBC data •Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen &/or result info. displayed | yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes yes yes user or vendor — yes yes yes | yes yes 10,000 results 10,000 results 10,000 results yes yes yes yes yes yes user or vendor yes yes yes |
| LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A | LIS1/LIS2 CLSI numeric & flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders no n/a yes, Abbott Accelerator DM enhanced QC, data archiving, data collation from multiple instruments — Codabar, codes 39 & 128, interl. 2 of 5, ISBT yes | proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no n/a yes, proprietary enhanced QC, data archiving, data collation from multiple instruments Lab-InterLink (planned), MDS/AutoLab, Roche (planned), Labotix (planned) Codabar, codes 39 & 128, interl. 2 of 5 yes |
| Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mfr. can perform diagnostics via modem | daily: 30 sec; weekly: 5 min; monthly: 10 min yes varies yes/no yes | daily: 30 sec; bi-weekly: 5 min; monthly: 10 min yes same day yes/no 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 a better diff.; retic with reportable IRF (immature retic. fraction); 60-species veterinary package |

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High-volume hematology analyzers

| Part 3 of 12 | Abbott Hematology Jeff Kolberg jeff.kolberg@abbott.com 5440 Patrick Henry Dr. Santa Clara, CA 95054 800-933-5535 www.abbottdiagnostics.com | Bayer HealthCare Diagnostics Fred Stelling 511 Benedict Ave. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com |
|---|--|---|
| See related article, page 12 | | |
| Name of instrument | CELL-DYN 3200 | Advia 120 Hematology System |
| First year installed in U.S./outside U.S./No. of units sold in 2005 | 1997/1997/— | 1998/1998/— |
| No. units installed in U.S./outside U.S./list price | n/a/n/a/\$165,000 | >750/3,400/\$169,000–\$189,000 |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, % neut, mono, lymph, eos, baso | •Chartable •Laboratory •Flags | standard menu (left) plus: RDW, MPV band #&%, IG #&%, variant lymph #&%, blast #&%, PCT, PDW, NRBC #&% band, IG, variant lymph, blast, NRBC, NWBC, RRBC, FWBC, RBC morph., high/low interp. message, LRI, URI, LURI, WBC |
| FDA-cleared tests but not clinically released | none | standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHR, CHCMr, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono; cellular Hgb %: hypo, hyper, macro, micro; calc. Hb, MPXI; %: blasts, PMN, MN; large Plt count; RBC frag. count; RBC ghost count left shift, atyp. lymph, blasts, immature grans, myeloperox. deficiency, aniso, micro, macro, Hb variation, hypo, hyper, NRBC, RBC frag., RBC ghost, large Plt, Plt clumps |
| Tests not available but submitted for clearance | none | none |
| Tests in development | none | IRF, MPC, MPM |
| For research use only | atypical depolarization flag outside U.S. | CSF, eos |
| Tests unique to analyzer | 3-D optical RBC analysis with advanced MCV measurement | CHCM, HDW, Chr, CHCMr, MPC, MPM; CSF: WBC, RBC, PMN, neut, lymph, mono |
| Differential method(s) used | MAPSS (Multi-Angle Polarized Scatter Sep.) | perox-peroxidase cytochem. staining with light scatter & absorption; baso-cytochem. stripping with 2-angle laser light scatter |
| Linearity: | •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) | 0.02–400/0–7.0; CSF WBC 0–5,000/μL; CSF RBC 0–1,500/μL 0–22.5/5–3,500 30–180 (MCV) |
| Precision: | •WBC count/RBC count •Hb/platelet •MCV or Hct | 2.7%/1.2% 0.93%/2.93% 0.78% (MCV) |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | 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 | 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 •RBC •MCV or Hct •Platelet •Hb | NRBCs, lytic-resistant RBCs, Plt clumps, cryoglobulin and cryofibrinogen, fragile WBCs elevated WBC count, increased No. giant Pits, autoagglutination, in vitro hemolysis MCV: elevated WBC count, hyperglycemia, in vitro hemolysis, increased No. giant Pits WBC fragments, in vitro hemolysis, microcytic RBCs, cryoglobulins, Plt clumping, increased No. giant Pits elevated WBC count, incr. plasma substances (triglycerides, bilirubin, in vivo hemolysis), lyse-resistant RBCs see WBC |
| Interfering substances: differential | | cold agglutinins, extreme sickle cell none none high WBC, lip., extremely high bili., interfere with cyanmethb. only, none with direct cellular Hb (CHCM) incomplete lysis of RBCs, complete myeloperox. deficiency |
| Age- and sex-specific reference ranges | yes | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 71/71 | 120/120 |
| Recommended average frequency of calib. | 6 months verification | 6 months |
| •Modes calibrated/parameters calibrated | open & closed/WBC, RBC, Hb, MCV, Plt, MPV | open, closed, autosampler/all measured parameters |
| Frequency of blood/latex controls | as per regulatory requirement/n/a | once per shift/not required |
| Min. specimen vol. open/closed/sample dead vol. closed | 150 μL/250 μL/1 mL (sample loader) | 157 μL/157 μL/<300 μL (tube size dependent) |
| Tube sampling supported | yes | yes (2, 3, 5, 7 mL—all sizes—open tube) |
| Veterinary capability | no | yes |
| Microsample capability | yes | yes |
| Prepares microscopic slides automatically or flags problems for slide prep | yes | yes |
| If auto. slidemaker available, No. installed/list price | n/a/\$125,000 | Advia S60, >100/\$35,000 |
| Archives patient data for later comparison | yes | yes |
| Patient-specific archiving | yes | no |
| Max. archived data accessible when system online | 10,000 results | 10,000 samples |
| Memory capacity—numeric results—No. specimens | 10,000 results | 10,000 samples |
| Memory capacity—histo/cytograms—No. specimens | 10,000 results | 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 | 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 | 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 | proprietary (Spec 79) |
| 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; host query for demographics & orders |
| LOINC codes transmitted with results | no | no |
| How labs get LOINC codes for reagent kits | n/a | online documentation |
| Optional data mgmt. or collation system | yes, proprietary | yes (CentralLink) |
| • Software features | enhanced QC, data archiving, data collation from multiple instruments | enhanced QC, data archiving, data collation from multiple instruments, auto-validation, integrated diff. pad, remote diagnostics, remote workstations |
| Interface avail. or planned to auto. specimen-handling system | Lab-InterLink, MDS/Autolab, Roche (planned), Labotix | LabCell (Bayer) |
| 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 | daily: 15 min; weekly: 15 min; monthly: 15 min |
| Onboard maintenance records | yes | yes |
| Time from communication of problem to engineer on site | same day | territory dependent |
| Onboard diagnostics/limited to software problems | yes/no | yes/no |
| Mfr. can perform diagnostics via modem | in development | yes |
| 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 Pits; uses only 3 reagents; 3-D MCV | unique laser technology provides cellular Hb for RBCs and retics; 2-D Plt analysis that eliminates interference from RBC fragments and exclusion of large Pits; dual WBC counts with a linearity of up to 400,000; CSF assay |

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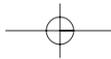


High-volume hematology analyzers

SURVEY
OF INSTRUMENTS

| | | |
|---|--|---|
| Part 4 of 12 | Bayer HealthCare Diagnostics Fred Stelling 511 Benedict Ave. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com | Bayer HealthCare Diagnostics Fred Stelling 511 Benedict Ave. Tarrytown, NY 10591 800-431-1970 www.bayerdiag.com |
| See related article, page 12 | | |
| Name of instrument | Advia 70 | Advia 2120 Hematology System |
| First year installed in U.S./outside U.S./No. of units sold in 2005 | 2001/2001/— | 2004/2004/— |
| No. units installed in U.S./outside U.S./list price | 100/400/\$89,000 | >200/>900/\$225,000 |
| Test menu: | •Chartable standard menu (left) plus: RDW, MPV | standard menu (left) plus: CHCM, MPV, RDW, HDW, LUC %&#, retic %&#, CHR, CHCMr, cellular Hgb, MCVr; CSF: WBC, RBC, PMN, MN, neut, lymph, mono % hypo, hyper, macro, micro; MPXI, % blast, PMN, MN, large Pit count, RBC fragment count; RBC ghost count, NRBC |
| All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | •Laboratory none | — |
| FDA-cleared tests but not clinically released | •Flags diff., WBC, N, B, L, RBC, ABN, PL, Cl, Pit/RBC | — |
| Tests not available but submitted for clearance | — | none |
| Tests in development | — | MPC, MPM |
| For research use only | Pct, PDW | IRF, CSF, eos |
| Tests unique to analyzer | — | CHCM, HDW, Chr, CHCMr, cellular Hgb, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono |
| Differential method(s) used | optical & enhanced impedance | 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) 0.1–99/0.02–9.99 | 0.02–400; CSF WBC 0–5,000/0–7.0; CSF RBC 0–1,500 |
| •Hemoglobin (g/dL)/platelet (10 ⁹ /L) | 1.5–30/10–2,000 | 0–22.5/5–3,500 |
| •MCV (fL) or Hct (%) | 30–150 (MCV) | 30–180 (MCV) |
| Precision: | •WBC count/RBC count 2.0%/1.2% | 2.7%/1.2% |
| •Hb/platelet | 1.0%/3–10% | 0.93%/2.93% |
| •MCV or Hct | 1.0% (MCV) | 0.78% (MCV) |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | neut% r=0.983, y=1.02x-3.3; lymph% r=0.983, y=0.96x+1.4; mono% r=0.797, y=1.02x+1.8; eos% r=0.963, y=0.91x+0.1; baso% r=0.322, y=0.30x+0.1 | 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 | incomplete RBC lysis cold agglutinins extremely high white blood cell count (Hct) RBC fragments lipemia, elevated WBC | incomplete RBC lysis (peroxidase only) cold agglutinins, extreme sickle cell none none extreme lipemia, high WBC, extreme high bili. interference w/ colorimetric Hb only, none with cellular Hb incomplete RBC lysis, complete myeloperox. deficiency |
| Interfering substances: differential | NRBCs, unlysed RBC, platelet clumps | |
| Age- and sex-specific reference ranges | yes | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 70/70 | 120/120 |
| Recommended avg. frequency of calib. | every 6 months per governmental requirements | 6 months |
| •Modes calibrated/parameters calibrated | open & closed/all measured parameters | autosampler, closed, open/all measured parameters |
| Frequency of blood/latex controls | one level per shift/not required | once per shift/not required |
| Min. specimen vol. open/closed/sample dead vol. closed | 90 µL/180 µL/120 µL | 175 µL/175 µL/<300 (tube size dependent) |
| Tube sampling supported | yes (12x75) | yes (2, 3, 5, 7 mL—all sizes open) |
| Veterinary capability | no | yes |
| Microsample capability | yes | yes |
| Prepares microscopic slides automatically or flags problems for slide prep | yes | if integrated to Advia Autoslide |
| If auto. slidemaker available, No. installed/list price | Advia S60,>100/\$35,000 | Advia Autoslide, n/a/\$98,000 |
| Archives patient data for later comparison | yes | yes |
| Patient-specific archiving | yes | no |
| Max. archived data accessible when system online | 100,000 | 10,000 |
| Memory capacity—numeric results—No. specimens | 100,000 | 10,000 |
| Memory capacity—histo/cytograms—No. specimens | 100,000 | 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 | user or vendor |
| Some results can be transmitted to LIS while others held | all results for that sample are transmitted at once | 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, ASTM 1394, E 1381 | proprietary |
| Information transferred on LIS interface | numeric & flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast | 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 |
| How labs get LOINC codes for reagent kits | online documentation | online documentation |
| Optional data mgmt. or collation system | in development | yes (Centralink) |
| • Software features | — | enhanced QC, data archiving, data collation from multiple instruments, auto validation, integrated diff. pad, remote diagnostics, remote workstations |
| Interface avail. or planned to auto. specimen-handling system | — | LabCell (Bayer) |
| Bar-code symbologies read on tube | Codabar, code 39, 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: 0; weekly: 0; monthly: 20 min | daily: 0; 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 |
| Mfr. can perform diagnostics via modem | in development | yes |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | microsampling; auto recount; dual WBCs; automatic wakeup and shutdown; no daily or weekly maintenance | unique laser technology provides direct 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 |

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

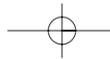


High-volume hematology analyzers

| Part 5 of 12 See related article, page 12 | Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com | Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com |
|--|--|--|
| Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2005 No. units installed in U.S./outside U.S./list price | LH 1500 Hematology Automation Series 2002/2003/14 >40/10/varies | LH 780 2006/2007/— n/a/—/\$214,500 |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %neut, mono, lymph, eos, baso FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer | •Chartable •Laboratory •Flags n/a n/a n/a MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD) IVD: NRBC, body fluids; RUO: MSCV, WBC RPD | standard menu (left) plus: RDW, RDW-SD, MPV, Retic %&#, IRF, MPV, graded RBC morph, NRBC %&#, TNC & RBC on CSF, synovial and serous fluids n/a 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 n/a n/a n/a RSF, MAF, MSCV, HLR %&#, RDWR-CV, RDWR-SD, PDW, PCT, WBC research population data (RPD) IVD: NRBC, body fluids, RDW-SD; RUO: MSCV, RSF, MAF, WBC RPD |
| Differential method(s) used Linearity: •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation Interfering substances: •WBC •RBC •MCV or Hct •Platelet •Hb Interfering substances: differential | Coulter's 3-D VCS biophysical flow cytometry with Intellikinetix, AccuGate & AccuFlex technologies 0-400/0-8.0 0-25/0-3,000 50-200 (MCV) <1.7%/<0.8% <0.8%/<3.3% <0.8% (MCV) lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins very high WBC, high conc. large Plt, autoagglutinins very small RBCs & WBC frags. may interfere very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing | Coulter's 3-D VCS biophysical flow cytometry with Intellikinetix, AccuGate & AccuFlex technologies 0-400/0-8.0 0-25/0-3,000 50-200 (MCV) <1.7%/<0.8% <0.8%/<3.3% <0.8% (MCV) lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins very high WBC, high conc. large Plt, autoagglutinins (MCV) very small RBCs & WBC frags. very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing |
| Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended avg. frequency of calib. •Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If auto. slidemaker available, No. installed/list price | yes 105 per analyzer on automation system/105 per analyzer on automation sys. as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hb, MCV, Plt, MPV per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL, 550 µL with slidemaker/1.0 mL yes no yes yes >850 U.S./\$110,000 | yes 105/105 as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hgb, MCV, Plt, MPV per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL (550 µL with slidemaker)/1.0 mL yes no yes yes —/\$110,000 |
| Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens •Stored in conjunction with CBC data •Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen &/or result info. displayed | yes yes 20,000 samples 20,000 samples 5,000 samples yes yes yes yes yes yes user or vendor yes yes yes yes | yes yes 20,000 results 20,000 results 5,000 results yes yes yes yes yes user or vendor yes yes yes yes |
| LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A | RS-232 numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast no — yes, Orchard Software Aqueduct, DL2000, Command Central enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results & graphics Beckman Coulter Codabar, codes 39 & 128, interl. 2 of 5, NW7 yes | proprietary numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast no contact technical support yes, DL2000, Command Central, Orchard Software Aqueduct enhanced QC, data archiving, data collection from multiple instruments, extensive decision rules, delta checking, patient results & graphics, centralized result management Beckman Coulter Codabar, codes 39 & 128, interl. 2 of 5 yes |
| Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mfr. can perform diagnostics via modem | daily: automation system= 5 min, analyzer=0; weekly: automation=10 min, analyzer=0; monthly: automation=15 min, analyzer=2 min yes — yes/no yes | daily: 0; weekly: 0; monthly: 2 min yes — yes/no yes |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | the LH 1500 hematology automation system automatically loads and unloads cassettes, performs reflex and repeat testing, sorts tubes for offline tests, stores tubes with availability for retrieval for any type of test; multiple configurations available; RUO: WBC research population data | extensive onboard user-defined decision support; extended linearity for WBC and Plt using AccuCount technology; enumeration of NRBCs with every differential; random access/automation ready; integrated slidemaker/slidestainer options; proservice; electronic IQAP; expanded QC module; RUO: WBC research population data |

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





High-volume hematology analyzers

| Part 6 of 12 See related article, page 12 | Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com | Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com |
|--|--|--|
| Name of instrument First year installed in U.S./outside U.S./No. of units sold in 2005 No. units installed in U.S./outside U.S./list price | Coulter LH 750/LH 755 2001/—/460 >2,000/>1,800/LH 750: \$195,000; LH 755: \$367,500 | Coulter LH 500 2003/2003/334 >780/>1,400/\$145,000 |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso •Chartable •Laboratory •Flags FDA-cleared tests but not clinically released Tests not available but submitted for clearance Tests in development For research use only Tests unique to analyzer | standard menu (left) plus: RDW, MPV, retic %&#, IRF, MPV, graded RBC morph, NRBC %&#, TNC & RBC on CSF, synovial and serous fluids — 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 n/a n/a n/a MSCV, HLR %&#, PDW, PCT, WBC research population data (RPD) IVD: NRBC, body fluids; RUO: MSCV, WBC RPD | standard menu (left) plus: retic #, retic %, MRV, IRF, RDW, MPV — user-definable age-, gender- &/or location-based ref. intervals, action & critical limits; user-def. RBC morph.; gradient msgs. none none none PCT, PDW none |
| Differential method(s) used Linearity: •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) Precision: •WBC count/RBC count •Hb/platelet •MCV or Hct Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation Interfering substances: •WBC •RBC •MCV or Hct •Platelet •Hb Interfering substances: differential | Coulter's 3-D VCS biophysical flow cytometry with IntelliKinetics, AccuGate & Accuflex technologies 0-400/0-8.0 0-25/0-3,000 50-200 (MCV) <1.7%/<0.8% <0.8%/<3.3% <0.8% (MCV) lymph% = ±3.0%, n/a; neut% = ±3.0%, n/a; mono% = ±2.0%, n/a; eos% = ±1.0%, n/a; baso% = ±1.0%, n/a unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, giant Plt, Plt clumps very high WBC, high conc. large Plt, autoagglutinins MCV & Hct: very high WBC, high conc. large Plt, autoagglutinins very small RBCs & WBC frags. may interfere very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs high triglycerides may affect lysing | Coulter's 3-D biophysical flow cytometry with AccuGate 500, Reaction Manager technologies 0-200/0-8.0 0-25/0-2,000 50-150 (MCV) 2.5%/≤2.0% 1.5%/≤5.0% 2% (MCV) 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 lyse-resistant, nucleated RBCs, frag. WBCs, agglut. WBCs, unlysed particles >35 fL, very large or agg. Plts, fibrin, cell frag., or other debris very high WBC count, many very large Plts, agglut. RBCs, RBCs <36 fL, fibrin, cell fragments, or other debris MCV: very high WBC count, high concentration of very large Plts, agglut. RBCs, RBC fragments <36 fL, rigid RBCs very small red cells near the upper threshold, cell fragments, clumped Plts, Plt frag. or cellular debris near the lower Plt threshold, giant Plts, Plt clumps, red & white cell frag., electronic noise, very small red cells very high WBC count, severe lipemia, heparin, lyse-resistant RBCs, turbidity such as elevated triglycerides factors that affect WBC count above or high triglycerides that affect lysing, hypogran. granulocytes, agranul. granulocytes, lyse-resist. red cells, very small or multi-population lymphocytes, elevat. trigly., precipitated elev. proteins |
| Age- and sex-specific reference ranges Max. CBCs per hr/max. CBCs & diffs. per hr Recommended average frequency of calib. •Modes calibrated/parameters calibrated Frequency of blood/latex controls Min. specimen vol. open/closed/sample dead vol. closed Tube sampling supported Veterinary capability Microsample capability Prepares microscopic slides automatically or flags problems for slide prep If auto. slidemaker available, No. installed/list price | yes 105/105 as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hb, MCV, Plt, MPV per CLIA, CAP, JCAHO, state or lab SOP/once per day 200 µL/300 µL, 550 µL with slidemaker/1.0 mL yes (multiple sizes & styles) no yes yes, both >850 U.S./\$110,000 | yes 75/75 as dictated by your lab procedures, local or national regulations primary/RBC, WBC, Hb, MCV, Plt, MPV not specified/once per day 125 µL/185 µL/tube dependent yes (10.25 x 75 mm or less; 13 x 75 mm or less) no yes no — |
| Archives patient data for later comparison Patient-specific archiving Max. archived data accessible when system online Memory capacity—numeric results—No. specimens Memory capacity—histo/cytograms—No. specimens •Stored in conjunction with CBC data •Histo/cytogram images & CBC data printed as 1 report Saved results can be recalled and retransmitted Saved data can be sorted for reprocessing or report transmission Performs delta checks Tags and holds results for followup, confirm. testing, or rerun Parameters for flags for holding samples are defined by Some results can be transmitted to LIS while others held Scattergram display: cell-specific color Histogram display: color with threshold Choice of desired specimen &/or result info. displayed | yes yes 20,000 samples 20,000 samples 5,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes | yes yes 20,000 samples 20,000 samples 5,000 samples yes yes yes yes yes yes yes yes yes yes yes yes yes yes |
| LIS interface formats supported Information transferred on LIS interface LOINC codes transmitted with results How labs get LOINC codes for reagent kits Optional data mgmt. or collation system • Software features Interface avail. or planned to auto. specimen-handling system Bar-code symbologies read on tube Accommodates bar-code placement per NCCLS standard Auto2A | RS-232, proprietary numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, Orchard Software Aqueduct, DL2000, Command Central enhanced QC, data archiving, common database, extensive decision rules, delta checking, patient results & graphics, centralized management of all instruments Beckman Coulter Codabar, codes 39 & 128, interl. 2 of 5, NW7 yes | RS-232, proprietary numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast no technical support yes, DL2000, Command Central, Orchard Software Aqueduct enhanced QC, data archiving, data collation from multiple instruments, common database, extensive decision rules, delta checking, patient results & graphics, centralized management of instruments — Codabar, codes 39 & 128, ASTM, interl. 2 of 5, NW7 yes |
| Time required for maintenance by lab personnel Onboard maintenance records Time from communication of problem to engineer on site Onboard diagnostics/limited to software problems Mfr. can perform diagnostics via modem | daily: 0; weekly: 0; monthly: 2 min yes — yes/no yes | none yes — yes/no yes |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | extensive decision support; enumeration of NRBCs with every diff; random access; automation ready; linearity for WBC and Plts; RUO: WBC RPD | extensive decision support, extended linearity for WBC & Plt, lowest review rate in class, small footprint, superior reliability, ProService, electronic IQAP |

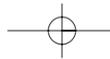
Tabulation does not represent an endorsement by the College of American Pathologists



High-volume hematology analyzers

| | | |
|--|---|---|
| Part 7 of 12 | Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com | Beckman Coulter Inc. Mary Beth Johnson mbjohnson@beckman.com 200 S. Kraemer Blvd. Brea, CA 92822-8000 714-993-8438 www.beckmancoulter.com |
| <i>See related article, page 12</i> | | |
| Name of instrument | Coulter HmX | Coulter Ac•T 5diff Family; Ac•T 5diff AL |
| First year installed in U.S./outside U.S./No. of units sold in 2005 | 1999 HmX AL, 1999 HmX CP/133 | 2001/2000; 2003/2003; open vial-5, cap pierce-200, autoloader-122 |
| No. units installed in U.S./outside U.S./list price | AL: 1,175/2,100/\$135,000; CP: 105/250/\$120,000 | 900/3,000/\$43,500 cap pierce model; \$38,500 open vial model; AL: 30/—; 300/750/\$54,500 autoloader model |
| Test menu: | <ul style="list-style-type: none"> •Chartable •Laboratory •Flags | <ul style="list-style-type: none"> •Laboratory •Flags |
| All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | standard menu (left) plus: RDW, MPV, retic #&%, graded RBC morph., IRF, MRV | standard menu (left) plus: RDW, MPV |
| FDA-cleared tests but not clinically released | comprehensive high/low, definitive & suspect messages | atyp. lymph. # (ATL#), atyp. lymph % (ATL%), immature cells # (IMM#), immature cells % (IMM%), PCT, PDW |
| Tests not available but submitted for clearance | none | complete operator selectable flagging |
| Tests in development | none | none |
| For research use only | PCT, PDW | PCT, PDW, IMM, ATL |
| Tests unique to analyzer | none | none |
| Differential method(s) used | Coulter's 3-D VCS technology | A•V technology combining cytochemistry, focused flow impedance, and light absorbance principles of measurement |
| Linearity: | <ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%) | <ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%) |
| Precision: | <ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct | <ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | 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 | 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 | unusual RBC abnormalities that resist lysing, NRBC, frag. WBC, unlysed particle >35 fL, large Plt | NRBCs, Plt clumps, large Plts, lyse-resistant RBCs |
| •RBC | very high WBC, high conc. of very large Plt, autoagglutinins | cold agglutinins, Plt clumps, WBC overlinearity |
| •MCV or Hct | MCV & Hct: very high WBC, high conc. of large Plt, autoagglutinins | Hct: lipemic samples, high WBC, cold aggluts |
| •Platelet | very small RBCs & WBC frags. may cause no fit | RBC and WBC fragments |
| •Hb | very high WBC, severe lipemia, heparin, rare lyse-resistant RBCs | elevated WBC, lipemia |
| Interfering substances: differential | high triglycerides may affect lysing | lyse-resistant RBCs, NRBCs, lipemia |
| Age- and sex-specific reference ranges | gender-specific printout | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 75/75 | 60/60; 80/80 |
| Recommended average frequency of calib. | timing not specified | not specified by time |
| •Modes calibrated/parameters calibrated | primary/RBC, WBC, Hb, MCV, Plt, MPV | open or closed/RBC, WBC, Hb, Hct, Plt |
| Frequency of blood/latex controls | not specified/once per day | not specified/none |
| Min. specimen vol. open/closed/sample dead vol. closed | 125 µL/185 µL/50 µL predilute/0.5 mL | 30 µL for CBC/30 µL/varies by tube size; 53 µL for CBC-diff/53 µL for CBC-diff./varies by tube size |
| Tube sampling supported | yes (multiple sizes & styles) | yes (multiple sizes) |
| 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 | no |
| Max. archived data accessible when system online | 5,000 samples | 10,000 samples |
| Memory capacity—numeric results—No. specimens | 5,000 samples | 10,000 samples |
| Memory capacity—histo/cytograms—No. specimens | 5,000 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 | 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 | yes, through user-defined criteria |
| Scattergram display: cell-specific color | 4 colors/cell types | no |
| Histogram display: color with threshold | colors without thresholds | yes |
| Choice of desired specimen &/or result info. displayed | no | yes |
| LIS interface formats supported | RS-232, proprietary | proprietary; proprietary ASTM |
| Information transferred on LIS interface | numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast | numeric & flag results, histograms & diff. plots, 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, Orchard Software Aqueduct | yes, DL2000, Command Central, Orchard Software Aqueduct |
| • Software features | enhanced QC, data archiving, common database, delta checking, patient results & graphics | enhanced QC, data archiving, common database, optional data mgmt., extensive decision rules, delta checking, patient results & graphics available, centralized management of all instruments |
| Interface avail. or planned to auto. specimen-handling system | Beckman Coulter | no |
| Bar-code symbologies read on tube | Codabar, codes 39 & 128, interl. 2 of 5, NW7 | Codabar, codes 39 & 128, interl. 2 of 5, EAN 8 & 13 |
| Accommodates bar-code placement per NCCLS standard Auto2A | no | yes |
| Time required for maintenance by lab personnel | none | none |
| Onboard maintenance records | no | yes |
| Time from communication of problem to engineer on site | — | — |
| Onboard diagnostics/limited to software problems | yes/no | yes/no |
| Mfr. 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 | 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 * linearity stated for Ac•T 5diff CP |

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

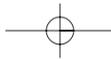


High-volume hematology analyzers

| | | |
|---|--|---|
| Part 8 of 12 | Horiba ABX Diagnostics Inc. Jim Knowles jknowles@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com | Horiba ABX Diagnostics Inc. Jim Knowles jknowles@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com |
| See related article, page 12 | | |
| Name of instrument | Pentra 60C+ Hematology Analyzer | Pentra XL 80 |
| First year installed in U.S./outside U.S./No. of units sold in 2005 | 2000/2000/52 | 2004/2003/33 |
| No. units installed in U.S./outside U.S./list price | 330/616/\$49,500 | 69/126/\$90,000 |
| Test menu: | •Chartable standard menu (left) plus: RDW, MPV atyp. lymph, atyp. lymph %, LIC, LIC % •Laboratory operator selectable flagging •Flags | standard menu (left) plus: automatic dilution of overrange results (WBC x 3, RBC/hgb/Pit x 2), RDW, MPV atyp. lymph, atyp. lymph%, LIC, LIC% operator selectable flagging |
| All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, 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 | — |
| For research use only | none | none |
| Tests unique to analyzer | none | automatic dilution protocol |
| Differential method(s) used | DHSS technology combining cytochemistry, focused flow impedance, & light absorbance principles of measurement | DHSS technology combining cytochemistry, focused flow impedance & light absorbance |
| Linearity: | •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) 0-120/0-8 •Hemoglobin (g/dL)/platelet (10 ⁹ /L) 0.7-24/0-1,900 •MCV (fL) or Hct (%) 0.7-67% (Hct) | 0-120/0-8 0-24/0-1,900 (>2 g/dL Hb) 0-67% (Hct)/0-2,800 (<2 g/dL Hb) |
| Precision: | •WBC count/RBC count <2%/<2% •Hb/platelet <1%/<5% •MCV or Hct <2% (Hct) | <2%/<2% <1%/<5% <2% (Hct) |
| Accuracy of automated diff. compared with manual diff. (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, n/a; baso% r=0.54, n/a | 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, lyse-resistant RBCs •RBC cold agglutinins •MCV or Hct Hct: extreme leukocytosis •Platelet microcytes, Plt clumps •Hb extreme lipemia/leukocytosis | NRBCs, Plt clumps, lyse-resistant RBCs cold agglutinins Hct: extreme leukocytosis microcytes, Plt clumps extreme lipemia, leukocytosis |
| Interfering substances: differential | NRBC, lyse-resistant RBCs, extreme hyperbilirubinemia | NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia |
| Age- and sex-specific reference ranges | yes | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 60/60 | 80/80 |
| Recommended average frequency of calib. | 6 months | 6 months |
| •Modes calibrated/parameters calibrated | closed-open/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/30 µL for CBC & 53 µL for CBC + diff/— | 30 µL for CBC/53 µL for CBC + diff/0.5 mL |
| Tube sampling supported | yes (multiple sizes) | yes (autoloader 13 x 75; closed tube 16 sizes + micro) |
| Veterinary capability | yes | yes |
| Microsample capability | yes | yes |
| Prepares microscopic slides automatically or flags 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 backup drive | yes, with MultiLink Data Manager |
| Max. archived data accessible when system online | unlimited with backup drive | MultiLink Data Manager; 10,000 instrument only |
| Memory capacity—numeric results—No. specimens | 10,000, unlimited with backup drive | MultiLink Data Manager; 10,000 instrument only |
| Memory capacity—histo/cytograms—No. specimens | 10,000, unlimited with backup drive | MultiLink 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 | 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 | 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; patient demographics, LIS to instrument—broadcast | numeric & flag results, histograms & scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument— broadcast |
| LOINC codes transmitted with results | yes | n/a |
| How labs get LOINC codes for reagent kits | — | n/a |
| Optional data mgmt. or collation system | yes | yes (MultiLink) |
| • Software features | enhanced QC, data archiving with Data Manager | enhanced QC, data archiving, data collation from multiple instruments |
| Interface avail. or planned to auto. specimen-handling system | no | 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 | yes/yes | no/yes |
| Mfr. can perform diagnostics via modem | yes, with Data Manager | yes |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | reliable 5-part WBC diff. technology—MTBF over 200 days; small footprint; small sample size of 53 µL | compact 5-part differential instrument with autoloader and autodilution capability, autorerun feature, auto validation |

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



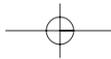


High-volume hematology analyzers

| | | |
|---|---|---|
| Part 9 of 12 | Horiba ABX Diagnostics Inc. Jim Knowles jknowles@us.abx.fr 34 Bunsen Irvine, CA 92618 888-903-5001 ext. 553 www.abx.com | System America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.systemex.com/usa |
| See related article, page 12 | | |
| Name of instrument | Pentra DX120 | System XE-2100 |
| First year installed in U.S./outside U.S./No. of units sold in 2005 | 2005/2004/6 | 2000/—/200 |
| No. units installed in U.S./outside U.S./list price | 14/70/\$196,000 | 1,050/3,700/\$225,000 |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | •Chartable •Laboratory •Flags | standard menu (left) plus: NRBCs, reticulocytes, IRF, MRV LIC%&#, atyp lymphs %&#, IMG %&#, IML %&#, IMM %&#, RETL%, RETM%, RETH%, IMR%, MRU, MFI%, CRC% |
| FDA-cleared tests but not clinically released | double-diff matrix pending 510 (k) | standard menu (left) plus: NRBC %&#, retic %&#, RDW-SD, RDW-CV, IRF, Plt-O, HPC#, MPV, IG%, IG# |
| Tests not available but submitted for clearance | double-diff matrix pending 510 (k) | none |
| Tests in development | double-diff matrix pending 510 (k) | 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 |
| For research use only | — | RET-He, IPF |
| Tests unique to analyzer | — | none |
| Differential method(s) used | cytochemistry (chlorazol black E) and absorbance | fluorescent flow cytometry, RF/DC detecting method |
| Linearity: | •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) | 0-440/0-8 0-25/0-5,000 0-75 (Hct) |
| Precision: | •WBC count/RBC count •Hb/platelet •MCV or Hct | <3%/<1.5% <1.0%/<4.0% <1.0% (Hct) |
| Accuracy of automated diff. compared with manual diff. (per NCCLS H-20A), regression equation | neut% r=0.99, n/a; lymph% r=0.98, n/a; mono% r=0.92, n/a; eos% r=0.97, n/a; baso% r=0.71, n/a | neut% r=0.95, y=0.92x+5.46; lymph% r=0.95, y=0.88x+2.46; mono% r=0.79, y=0.77x+1.88; eos% r=0.92, y=0.97x+0.29; baso% r=0.82, y=1.01x+0.01; NRBC% r=0.96, y=1.12x+0.11; IG% r=0.83, y=0.9332x+0.0922 |
| Interfering substances: •WBC •RBC | NRBCs, Plt clumps, lyse-resistant RBCs cold agglutinins | cold agglut., Plt aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs cold agglut., severe microcytosis, frag. RBCs, large No. giant Plts, in vitro hemolysis |
| •MCV or Hct | Hct: extreme leukocytosis | Hct: cold agglutinins, leukocytosis (>100,000/μL), ABN red cell fragility, spherocytosis |
| •Platelet •Hb | microcytes, Plt clumps extreme lipemia, leukocytosis | pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megalocytic Plts lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/μL) |
| Interfering substances: differential | NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia | lyse-resistant RBCs |
| Age- and sex-specific reference ranges | yes | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 120/120 | 150/150 |
| Recommended average frequency of calib. •Modes calibrated/parameters calibrated | 6 months open, closed/WBC, RBC, Hb, Hct, Plt, MPV | twice per year by FSR open, closed, capillary/WBC, RBC, Hb, Hct, Plt |
| Frequency of blood/latex controls | per CLIA standards/none | per 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 | yes | no |
| Microsample capability | yes, open mode | yes |
| Prepares microscopic slides automatically or flags problems for slide prep | yes | yes with Alpha or HST upgrade |
| If auto. slidemaker available, No. installed/list price | —/— | >1,000/price depends on configuration |
| Archives patient data for later comparison | yes | yes |
| Patient-specific archiving | yes | yes |
| Max. archived data accessible when system online | unlimited Data Manager; 10,000 instrument only | 10,000 samples |
| Memory capacity—numeric results—No. specimens | unlimited Data Manager | 10,000 samples |
| Memory capacity—histo/cytograms—No. specimens | unlimited Data Manager | 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 | user or vendor |
| 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 | yes |
| LIS interface formats supported | proprietary, ASTM 1394 & 1238, HL7, IEEE MIB | RS-232C/TCP IP |
| 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; host query for patient demographics & orders |
| LOINC codes transmitted with results | n/a | yes |
| How labs get LOINC codes for reagent kits | n/a | contact vendor |
| Optional data mgmt. or collation system • Software features | yes (MultiLink) enhanced QC, data archiving, data collation from multiple instruments | yes, proprietary enhanced QC, data archiving, data collation from multiple instruments, online QC |
| Interface avail. or planned to auto. specimen-handling system | yes | Roche, Labotix, IDS, A&T |
| Bar-code symbologies read on tube | Codabar, codes 39 & 128, ASTM, interl. 2 of 5 | 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 | weekly: 15 min | daily: 15 min walkaway with autoready |
| Onboard maintenance records | yes | yes |
| Time from communication of problem to engineer on site | — | territory dependent |
| Onboard diagnostics/limited to software problems | no/yes | yes/no |
| Mfr. can perform diagnostics via modem | yes | yes |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | high-throughput cell counter with integrated reticulocyte methodology and slidemaker/stainer; fluorescent NRBC counting, auto rerun and reflex testing, auto validation | enum. of NRBCs; throughput of 150 CBCs per hour; random access; discrete testing; HPC testing; online QC; remote diagnostics, IG enum., body fluid analysis; platelet linearity to 5 million, IPF, and RET He; hematocrit non-linear to 75% |

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

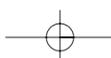


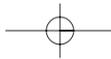


High-volume hematology analyzers

| | | |
|---|--|---|
| Part 10 of 12 | Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa | Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa |
| See related article, page 12 | | |
| Name of instrument | Sysmex XE-2100L | Sysmex XE-2100D |
| First year installed in U.S./outside U.S./No. of units sold in 2005 | 2001/—/20 | 2004/2004/12 |
| No. units installed in U.S./outside U.S./list price | 120/310/\$200,000 | 12/—/\$200,000 |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | <ul style="list-style-type: none"> •Chartable •Laboratory •Flags | <ul style="list-style-type: none"> standard menu (left) plus: MPV, RDW-SD, RDW-CV, NRBC %&#, HPC#, IG%, IG# none Plt clumps, Plt ABN distribution, WBC ABN scattergram, blast, left shift, atyp. lymph., ABN lymph./blasts, RBC ABN distribution, RBC lyse resistance, RBC agglut., turbidity none none none P-LCR, PCT, PDW HPC#, NRBC, IG%, IG# |
| FDA-cleared tests but not clinically released | none | n/a |
| Tests not available but submitted for clearance | none | n/a |
| Tests in development | none | n/a |
| For research use only | P-LCR, PCT, PDW | P-LCR, PCT, PDW |
| Tests unique to analyzer | HPC#, NRBC, IG%, IG# | IG% & IG# |
| Differential method(s) used | fluorescent flow cytometry, RF/DC detecting method | fluorescent flow cytometry |
| Linearity: | <ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%) | <ul style="list-style-type: none"> 0-440/0-8 0-25/0-5,000 0-75 (Hct) |
| Precision: | <ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct | <ul style="list-style-type: none"> 0-25/0-5,000 0-75 (Hct) ≤3%/≤1.5% ≤1.0%/≤4.0% ≤1.0% (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: | <ul style="list-style-type: none"> •WBC •RBC •MCV or Hct •Platelet •Hb | <ul style="list-style-type: none"> cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL) Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL) lyse-resistant RBCs |
| Interfering substances: differential | | |
| 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. | twice per year by FSR | twice 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 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 | 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, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders | 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 | 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, online QC | enhanced QC, data archiving, data collation from multiple instruments, online QC |
| Interface avail. or planned to auto. specimen-handling system | Roche, Labotix, A&T, IDS | Lab InterLink, MDS/AutoLab, Beckman Coulter, Roche, Labotix, A&T |
| 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: 15 min walkaway with autoready | daily: 15 min walkaway with autoready |
| Onboard maintenance records | yes | yes |
| Time from communication of problem to engineer on site | territory dependent | contract and territory dependent |
| Onboard diagnostics/limited to software problems | yes/no | yes/no |
| Mfr. 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, IG enumeration, body fluid analysis | provides high throughput sample analysis; small footprint; configurable & scalable; platelet linearity—5 million, hematocrit extended to 75% |

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



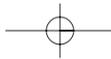


High-volume hematology analyzers

| | | |
|---|--|--|
| Part 11 of 12 | Sysmex America Inc. Nilam Patel 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa | Sysmex America Inc. Margaret Triola 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa |
| See related article, page 12 | | |
| 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 2005 | 2000/—/50 | 2002/—/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: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | <ul style="list-style-type: none"> •Chartable •Laboratory •Flags | <ul style="list-style-type: none"> standard menu (left) plus: RDW-SE, RDW-CV, IG%, IG#, NRBC%, NRBC#, retic%&#, IRG, Pit-O, HPC#, MPV none |
| FDA-cleared tests but not clinically released | standard menu (left) plus: retic %&#, IRF, Pit-O, MPV, RDW-SD, RDW-CV | standard menu (left) plus: retic %&#, IRF, Pit-O, MPV, RDW-SD, RDW-CV |
| Tests not available but submitted for clearance | none | none |
| Tests in development | Pit clumps, RBC agglut., turbidity, WBC ABN scattergram, RBC ABN distrib., Pit ABN distrib., RBC lyse resistance, blasts, left shift, atyp. lymph., ABN lymph./blast, ret. ABN scattergram | Pit clumps, Pit 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 |
| For research use only | new release IPF & RET He | body fluids |
| Tests unique to analyzer | none | immature gran. %&# |
| Differential method(s) used | fluorescent flow cytometry, RF/DC detecting method | fluorescent flow cytometry |
| Linearity: | <ul style="list-style-type: none"> •WBC count (10⁹/L)/RBC count (10¹²/L) •Hemoglobin (g/dL)/platelet (10⁹/L) •MCV (fL) or Hct (%) | <ul style="list-style-type: none"> 0–170/0–8 0–25/0–5,000 0–75 (Hct) |
| Precision: | <ul style="list-style-type: none"> •WBC count/RBC count •Hb/platelet •MCV or Hct | <ul style="list-style-type: none"> 0–60 (Hct) ≤3.0%/≤1.5% ≤1.5%/≤4.0% ≤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: | <ul style="list-style-type: none"> •WBC •RBC •MCV or Hct •Platelet •Hb | <ul style="list-style-type: none"> •WBC •RBC •MCV or Hct •Platelet •Hb |
| Interfering substances: differential | cold agglut., Pit aggreg., nucl. RBCs, cryoglob., lyse-resistant RBCs cold agglut., severe microcytosis, frag. RBCs, large No. giant Pits, in vitro hemolysis Hct: cold agglut., leukocytosis (>100,000/μL), ABN red cell fragility, spherocytosis pseudothrombocytopenia, Pit aggreg., incr. microcytosis, megalocytic Pits lipemia, ABN proteins in blood plasma, severe leukocytosis (>100,000/μL) lyse-resistant RBCs | cold agglut., Pit aggreg., cryoglob., lyse-resistant RBCs, NRBCs cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL) Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, Pit aggreg., incr. microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL) 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. | twice per year by FSR | every 6 months 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 CLIA requirements/not required | per CLIA requirements/not required |
| 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, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders | 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 | 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, online QC | enhanced QC, data archiving, data collation from multiple instruments, online QC |
| 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: 15 min walkaway with autoready | daily: 15 min walkaway with autoready |
| Onboard maintenance records | yes | yes |
| Time from communication of problem to engineer on site | territory dependent | contract and territory dependent |
| Onboard diagnostics/limited to software problems | yes/no | yes/no |
| Mfr. can perform diagnostics via modem | yes | yes |
| Acquisition program based on cost-per-reportable result | yes | yes |
| Distinguishing features | multiple configurations available as are all distinguishing features of the XE-2100; platelet linearity—5 million; new parameters for platelet monitoring—IPF & retic Hb measurement & RET He | 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; body fluids now FDA approved |

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High-volume hematology analyzers

| | | |
|---|---|--|
| Part 12 of 12 | Sysmex America Inc. Margaret Triola 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa | Sysmex America Inc. Margaret Triola 1 Nelson C. White Pkwy. Mundelein, IL 60060 800-379-7639 www.sysmex.com/usa |
| See related article, page 12 | | |
| 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 2005 | 2002/—/150 | 2005/2006/— |
| No. units installed in U.S./outside U.S./list price | 550/3,500/\$125,000 | released June 2006/200/\$85,000 (XS-1000i) \$95,000 (AutoLoader) |
| Test menu: All instruments have: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, %&# neut, mono, lymph, eos, baso | •Chartable •Laboratory •Flags | |
| FDA-cleared tests but not clinically released | standard menu (left) plus: MPV, RDW-SD, RDW-CV | standard menu (left) plus: MPV, RDW-SD, RDW-CV |
| Tests not available but submitted for clearance | none | none |
| Tests in development | 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 |
| For research use only | body fluids | none |
| Tests unique to analyzer | none | none |
| | immature gran. %&# | none |
| | IG%&# | n/a |
| | — | — |
| Differential method(s) used | fluorescent flow cytometry | fluorescent flow cytometry |
| Linearity: | •WBC count (10 ⁹ /L)/RBC count (10 ¹² /L) •Hemoglobin (g/dL)/platelet (10 ⁹ /L) •MCV (fL) or Hct (%) | 0-440/0-8 0-25/0-5,000 0-60 (Hct) |
| Precision: | •WBC count/RBC count •Hb/platelet •MCV or Hct | 0-400/0-8 0-25/0-5,000 0-60 (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 •RBC •MCV or Hct | cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs |
| | •Platelet •Hb | cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL) |
| Interfering substances: differential | cold agglut., Pit aggreg., incr. microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL) lyse-resistant RBCs | cold agglut., Plt aggreg., cryoglob., lyse-resistant RBCs, NRBCs cold agglut., severe microcytosis, frag. RBCs, leukocytosis (>100,000/μL) Hct: cold agglut., ABN red cell fragility, spherocytosis, leukocytosis (>100,000/μL) pseudothrombocytopenia, Plt aggreg., incr. microcytosis, megaloblasts lipemia, ABN proteins, leukocytosis (>100,000/μL) lyse-resistant RBCs |
| Age- and sex-specific reference ranges | yes | yes |
| Max. CBCs per hr/max. CBCs & diffs. per hr | 80/80 | 60 per hr/60 per hr |
| Recommended average frequency of calib. | every 6 months by FSR | minimum annually |
| •Modes calibrated/parameters calibrated | open, closed, capillary/WBC, RBC, Hb, Hct, Plt | 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 | 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 | yes |
| If auto. slidemaker available, No. installed/list price | — | 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, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics & orders | 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 | 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, online QC | enhanced QC, data archiving, data collation from multiple instruments, online QC; SNCS diagnostics |
| 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 |
| Accommodates bar-code placement per NCCLS standard Auto2A | yes | yes |
| Time required for maintenance by lab personnel | daily: 15 min walkaway with autoready | daily: 3 min; weekly: none; monthly: 9 min |
| Onboard maintenance records | yes | yes |
| Time from communication of problem to engineer on site | contract and territory dependent | contract and 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; discrete testing; reagent monitoring; chartable report formats; XT-V for use in toxicology & research; unique specimen-gating SW is FDA Part II compliant; body fluids now FDA approved | common technology to other "X" series analyzers; small sample volume requirements for CBC + 5 part diff; SNCS remote diagnostics capability |

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

