				HEMATOLOGY ANA	LYZERS	OCTOBER 2023 I CAP TODAY 45	
Part 1 of 12				Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.corelaboratory.abbott	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.corelaboratory.abbott	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.corelaboratory.abbott	
Name of inst First year inst No. units ins	rument alled in U.S./Outside U.S./ talled in U.S./Outside U.	/No. of units sold Sept. 2022- .S./List price [†]	–Aug. 2023	Alinity h-series* 2023/2017/— —/>770/—	CELL-DYN Emerald* 2009/2008/— >1.700/>2,800/\$30,000	CELL-DYN Emerald 22* 2016/2016/— —/—/\$64,000	
Menu of cha MCHC, PL1	rtable tests (standard m ', neut %&#, mono, lymį	nenu: WBC, RBC, Hb, Hct, M ph, eos, baso)	ICV, MCH,	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, neut %&#, mono %&#, lymph %&#, eos %&#, baso %&#, IG %&#, RDW, NRBC, NR/W, RETIC %&#, R %, IRF, MCHr, MPV, rP %</td><td>WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, lymph %&#, gran %&#, mid %&#, RDW, MPV</td><td>standard menu plus: RDW, MPV, mono %&#, lymph %&#, eos %&#, baso %&#</td></tr><tr><td>Tests submit Tests for res</td><td>ted for 510(k) clearance earch use only</td><td>3/Tests in development</td><td></td><td></td><td></td><td>_</td></tr><tr><td>Tests unique Differential r</td><td>to analyzer nethod(s) used</td><td></td><td></td><td></td><td>electrical impedance counting</td><td></td></tr><tr><td>Dinorenta</td><td></td><td></td><td></td><td>separation) technology using seven light scatter</td><td>libbinda impodatos counting</td><td></td></tr><tr><td>Analytical m</td><td>easurement range:</td><td>WBC count/RBC count Hemoglobin/Platelet MCV (fL) or Hct (%) Reticulocytes</td><td></td><td>detectors and one nuorescent detector $0.04-447.00 \times 10^3$ cells/µL/$0.01-8.08 \times 10^6$ cells/µL $0.15-24.1$ g/dL/$0.46-5,325 \times 10^3$ cells/µL 51.4-131.0</math> fL (MCV), $9.42-86.0%$ (Hct) $0.05-644 \times 10^3$ cells/µL</td><td>0.4–96.1 K/µL/0.22–7.61 M/µL 3.3–24.6 g/dL/9–1,375 K/µL 48.8–115 fL (MCV), 5.3–75.6% (Hct) —</td><td>0.4–90 K/µL/1.2–8.3 M/µL 5.5–22 g/dL/11–1,485 K/µL 53.2–118.4 fL (MCV), 12.1–66.1% (Hct) —</td></tr><tr><td>Precision:</td><td>• WBC count/RBC cou</td><td>unt</td><td></td><td>\leq3.5 CV% @ >4.0×10³ cells/µL/\leq1.5 CV% @</td><td>3.5% (95% confidence limit)/2.0% (95% confid. limit)</td><td>3.2% CV/2.0% CV</td></tr><tr><td></td><td>Hemoglobin/Platelet MCV or Hct Beticulocytes</td><td>t</td><td></td><td>>4.00×10° cells/µL ≤1.3 CV% @ >12.0 g/dL/≤4.5 CV% @ >50.00×10³ cells/µL ≤1.0 CV% (MCV), ≤2.0 CV% for Hct >45% <7.0 CV% @ >200.00×10³ cells/µl</td><td>2.1% (95% confidence limit)/6.1% (95% confid. limit) 0.8% MCV (95% confid. limit), 1.7% Hct (95% confid. limit)</td><td>1.2% CV/7.1% CV 0.8% CV (MCV)</td></tr><tr><td>Accuracy of</td><td>automated differential c</td><td>compared with manual</td><td></td><td></td><td>_</td><td>_</td></tr><tr><td>differential</td><td>(per CLSI H20-A2)</td><td></td><td></td><td>errodokulin errofikringen fragile WRCs nonviable</td><td>ervedebulin ervefibringen benarin menedenal proteins</td><td>errodokulin errofibringen, henarin monoclonal proteins</td></tr><tr><td>littering or</td><td>• RBC</td><td></td><td></td><td>WBCs, neutrophil aggregates, hemoglobin C crystals, NRBCs, PLT clumps/aggregates RBC autoagglutinins, cold agglutinins, giant PLTs, RBC fragments</td><td>cryoglobulin, cryofibrinogen, nepaint, monocorra protons, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), autoagglutination, clotting, in vitro hemolysis microcytic red cells</td><td>cryoglobulin, cryofibrinogen, nepanit, monocorra protons, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells</td></tr><tr><td></td><td>• MCV (</td><td>or Hct</td><td></td><td>RBC autoagglutinins, cold agglutinins, giant PLTs, PLT clumps/aggregates, hyperglycemia</td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), hyperglycemia (>600 mg/dL), autoagglutination, clotting, in vitro hemolysis, more</td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), hyperglycemia (>600 mg/dL), autoagglutination, clotting, in vitro hemolysis, more</td></tr><tr><td></td><td>• Platel</td><td>et</td><td></td><td>RBC autoagglutinins, cold agglutinins, cryoglobulin, cryofibrinogen, giant PLTs, PLT clumps/aggregates, PLT satellitism, RBC fragments, more</td><td>cryoglobulin, cryofibrinogen, in vivo and in vitro hemolysis, microcytic red cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin, platelet, more</td><td>cryoglobulin, cryofibrinogen, in vivo and in vitro hemolysis, microcytic red cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin, platelet, more</td></tr><tr><td></td><td>• Hemo</td><td>globin</td><td></td><td>hemoglobin C crystals</td><td>carboxyhemoglobin (>10%), cryoglobulin, cryofibrinogen, in vivo hemolysis, heparin, high white cell count (>50,000 K/μL), hyperbilirubinemia, lipemia, monoclonal proteins, clotting</td><td>carboxyhemoglobin (>10%), cryoglobulin, cryofibrinogen, in vivo hemolysis, heparin, high white cell count (>50,000 K/μL), hyperbilirubinemia, lipemia, monoclonal proteins, clotting</td></tr><tr><td></td><td>• Reticu</td><td>ulocytes</td><td></td><td>RBC autoagglutinins, cold agglutinins, babesiosis, malaria, basophilic stippling, giant PLTs, PLT clumps/aggregates, Howell-Jolly bodies, Heinz bodies, RBC autofluorescence</td><td>_</td><td>-</td></tr><tr><td>Interfering su</td><td>ibstances: differential</td><td></td><td></td><td>cryoglobulin, cryofibrinogen, fragile WBCs, nonviable WBCs, neutrophil aggregates, hemoglobin C crystals, NRBCs, PLT clumps/aggregates</td><td>platelet aggregates, NRBCs, giant platelets, cryoglobulin, incomplete lysis of RBCs, small lymphocytes, fibrin clots, shift in WBC cell distrib. due to EDTA anticoagulant equilibration</td><td>platelet aggregates, erythroblasts, small lymphocytes, immature cells, resistant RBCs, giant or hypersegmented neutrophils, bands</td></tr><tr><td>Throughput: Minimum sp</td><td>max. CBCs per hour/Ma ecimen volume open/Cl</td><td>IX. CBCs and differentials periode to see the second se</td><td>er hour closed</td><td>—/119 ≤100 µL/≤100 µL/dependent on tube</td><td>57/57 9.8 μL/—/—</td><td>45/45 17 μL/—/—</td></tr><tr><td>Microsample Instrument p</td><td>capability repares microscope slic</td><td>des automatically/No. of aut</td><td>tomatic</td><td>no yes/>150</td><td>no no/</td><td>no no/—</td></tr><tr><td> slide make Slide make </td><td>rs installed</td><td>ly or combined unit</td><td></td><td>sold as combined unit</td><td>_</td><td>_</td></tr><tr><td>Instrument a</td><td>rchives patient data/Arc</td><td>chiving is patient specific</td><td>lino</td><td>yes/yes</td><td>yes/no 200,000 on USB and 1,500 results on internal memory</td><td>yes/no 200,000 on USB and 1,000 records with histograms on</td></tr><tr><td>Waximum a</td><td>Nount of archived data a</td><td>ACCESSIBLE WHEN System on</td><td>line</td><td>_</td><td>300,000 on USB and 1,000 results on internal memory</td><td>internal memory</td></tr><tr><td>No. specime</td><td>ns for which numeric re</td><td>sults saved in memory at o</td><td>ince</td><td>most recent 100,000 results</td><td>300,000 on USB and 1,500 results on internal memory</td><td>300,000 on USB and 1,000 records with histograms on internal memory</td></tr><tr><td>No. specime</td><td>ns for which histo/cytog</td><td>ram results saved in memo</td><td>ory at once</td><td>most recent 100,000 results</td><td>300,000 on USB and 1,500 results on internal memory</td><td>300,000 on USB and 1,000 records with histograms on internal memory</td></tr><tr><td>Instrument p Parameters f Flagging is c</td><td>erforms delta checks or which flags may app merator selectable</td><td>iear</td><td></td><td>yes morphological flags including PLT clump, left shift, blast, variant LYM, RBC fragments, ASYM RBC, more operator and vendor selectable</td><td>no dispersional data alerts, suspect measurand flags, and count invalidation flags ves</td><td>no dispersional data alerts, suspect parameter flags, and count invalidation flags ves</td></tr><tr><td>Tags and hol</td><td>ds results for follow-up,</td><td>, confirmatory testing, or re-</td><td>run</td><td>yes</td><td>no</td><td>no</td></tr><tr><td>Scattergram</td><td>display: cell-specific co</td><td>lor</td><td>1001</td><td>yes</td><td>no</td><td>yes</td></tr><tr><td>Histogram di User interfac</td><td>splay: color with thresno e can display choice of</td><td>olds Especimen or result informa</td><td>ation</td><td>yes ves</td><td>no ves</td><td>yes ves</td></tr><tr><td>LIS interface Information t</td><td>formats supported ransferred via LIS interf</td><td>iace</td><td></td><td>ASTM 1394-91, ASTM 1381, HL7 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>proprietary numeric and flag results, instrument to LIS</td><td>proprietary numeric and flag results, instrument to LIS</td></tr><tr><td colspan=2>LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test</td><td>S/ test</td><td>Abbott ACCELERATOR 23600 Abbott GLP systems Track</td><td>no/no/no</td><td>no/no/no</td></tr><tr><td>Barcode sym</td><td>bologies read on specin</td><td>nen tube</td><td>- O - O</td><td>Codabar, Code 39, Code 128, Interleaved 2 of 5</td><td>Codabar, Code 39, Code 128, Interleaved 2 of 5, Chinese post, Code 93, EAN8, EAN13, EAN128, IATA, Industrial 2 of 5, Italian pharmaceutical, Matrix 2 of 5, MSI/Plessey, more</td><td>Codabar, Code 39, Code 128, Interleaved 2 of 5, Chinese post, Code 39 full ASCII, Code 93, EAN8, EAN13, EAN128, IATA, Industrial 2 of 5, Italian pharmaceutical, Matrix 2 of 5, more</td></tr><tr><td>No. of cleani</td><td>ng or maintenance reag</td><td>per GLSI standard Autooz-r dents required/No. of routin</td><td>42 1e</td><td>yes 1 (Alinity ha module)/3 CBC/diff, 1 retic</td><td>no 1/2</td><td>no 1/2</td></tr><tr><td>liquid read</td><td>jents required d for daily, weekly, mor</td><td>nthly maintenance</td><td></td><td>daily: 0 (automatic) for Alinity hq, hs modules;</td><td>dailv: none: weekly: ~15 min.; biannually: ~10 min.</td><td>dailv: none: weekly: 15 minutes; quarterly: ~10 minutes</td></tr><tr><td>Onboard dia</td><td>gnostics for troubleshoo</td><td>oting/Limited to software pr</td><td>oblems</td><td>weekly: 0 (automatic) for Alinity hq, hs modules yes/no</td><td>no/no</td><td>no/no</td></tr><tr><td>Manufacture</td><td>r can perform diagnostic</td><td>cs via modem</td><td></td><td>no</td><td>no</td><td>no</td></tr><tr><td></td><td>g lealures (supplied by</td><td>company)</td><td></td><td>http://www.initerance.com/provide/com/p</td><td>SMBIL: Sample Size, reagent volumes used, and physical size; reliable: averages one service call per year; easy to use: system has touchscreen software with intuitive icone and minimal layers</td><td>Small physical loop int, only 5 reagen is used (2 or 5 reagents stored onboard), and built-in monitor; automated start-up, shut down, and cleaning; 5-part differential using UNLER DW optical flow orthometry technology with a patented</td></tr><tr><td>Note: a dash</td><td>in lieu of an answer me</td><td>eans company did not ansv</td><td>ver</td><td>a3600 lab automation system and AlinIQ middleware</td><td></td><td>lyse allowing for clear separation of the 5 WBC populations</td></tr><tr><td colspan=2>question or question is not applicable</td><td>le</td><td></td><td>limitations, and precautions</td><td>*refer to CELL-DYN Emerald operator's manual for warnings, limitations, and precautions</td><td>*refer to CELL-DYN Emerald 22 operator's manual for warnings, limitations, and precautions</td></tr></tbody></table>			

TO CALIFOLATI OUTODEN 2023		HEIMATOLOGY ANA	LYZERS	
Part 2 of 12		Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.corelaboratory.abbott	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.corelaboratory.abbott	Advanced Instruments Julie Mackenzie glocyte@aicompanies.com Norwood, MA 781-320-9000 www.aicompanies.com
Name of instrument First year installed in U.S./Outside U.S./No. of units sold No. units installed in U.S./Outside U.S./List price [†]	Sept. 2022–Aug. 2023	CELL-DYN Emerald 22 Autoloader* 2019/—/— —/—/\$75,000	CELL-DYN Ruby* 2006/2006/ >550/>2,700/\$185,000	GloCyte Automated Cell Counter for CSF 2016/2018/—
Menu of chartable tests (standard menu: WBC, RBC MCHC, PLT, neut %&#, mono, lymph, eos, baso) Tests submitted for 510(k) clearance/Tests in develo	, Hb, Hct, MCV, MCH, opment	standard menu plus: RDW, MPV, mono %&#, lymph %&#, eos %&#, baso %&# </td><td>standard menu plus: MPV, RDW, retic %&#, mono %&#, lymph %&#, eos %&#, baso %&# —</td><td>RBC, TNC</td></tr><tr><td>Tests for research use only</td><td></td><td>—</td><td></td><td>_</td></tr><tr><td>lests unique to analyzer</td><td></td><td></td><td>atypical depolarization flag</td><td>_</td></tr><tr><td>Analytical measurement range: • WBC count</td><td>'RBC count</td><td>0.4–90 K/µL/1.2–8.3 M/µL</td><td>$0.02-246 \times 10^{3}$/µL/0.00-7.50 × 10^{6}/µL</td><td>— TNC: 3–123 cells/μL (reportable range, 3–6,500 cells/μL)/ 2–123 cells/μL (reportable range, 2–615,644 cells/μL)</td></tr><tr><td> Hemoglobin MCV (fL) or Reticulocytic </td><td>n/Platelet Hct (%) es</td><td>5.5–22 g/dL/11–1,485 K/μL 53.2–118.4 fL (MCV), 12.1–66.1% (Hct) —</td><td>0.00–25.0 g/dL/0.00–3,000 × 10³/µL 58–139 (MCV), 8.3–79.8% (Hct) —</td><td></td></tr><tr><td>Precision: • WBC count/RBC count</td><td></td><td>3.2% CV/2.0% CV</td><td>2.4%/1.8%</td><td>TNC: 2.5–18.0% repeatability CV/ 2.7–16.3% repeatability CV</td></tr><tr><td>Hemographic Field Hemographic Field MCV or Hct Reticulocytes</td><td></td><td>0.8% CV (MCV)</td><td>0.8% (MCV) 0.2–22.9%</td><td></td></tr><tr><td>Accuracy of automated differential compared with differential (per CLSI H20-A2)</td><td>nanual</td><td>neut% r=1.00, slope=0.97, y=1.88; lymph% r=0.99, slope=1.00, y=0.30; mono% r=0.92, slope=0.96, y=0.42; eos% r=0.97, slope=0.93, y=0.22; baso% r=0.63, slope=0.26, y=0.04</td><td>neut% r=0.983, slope=0.97, y=-1.98; lymph% r=0.921, slope=0.95, y=0.94; mono% r=0.711, slope=1.10, y=1.93; eos% r=0.952, slope=1.04, y=0.01; baso% r=0.146, slope=0.18, y=1.22</td><td>_</td></tr><tr><td>Interfering substances: • WBC</td><td></td><td>cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants</td><td>fragile WBC, neutrophil aggregates, lytic-resistant RBCs, NRBCs, PLT clumps, cryofibrinogen, cryoglobulin paraproteins</td><td>-</td></tr><tr><td>• RBC</td><td></td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/µL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells</td><td>elevated WBC, increased numbers of giant PLTs, autoagglutination, in vitro hemolysis</td><td>-</td></tr><tr><td>MCV or Hct</td><td></td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/µL), hyperglycemia (>600 mg/dL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells</td><td>MCV: elevated WBC, hyperglycemia, in vitro hemolysis, increased number of giant PLTs</td><td>_</td></tr><tr><td>• Platelet</td><td></td><td>cryoglobulin, cryofibrinogen, in vivo and in vitro hemolysis, microcytic red cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin, platelet clumping, platelet satellitosis</td><td>WBC fragments, in vitro hemolysis, microcytic RBCs, cryofibrinogen, cryoglobulin, PLT clumping, increased number of giant PLTs</td><td>_</td></tr><tr><td>• Hemoglobin</td><td></td><td>carboxyhemoglobin (>10%), cryoglobulin, cryofibrinogen, in vivo hemolysis, heparin, high white cell count (>50,000 K/µL), hynerbilirubinemia. linemia. monoclonal proteins. clotting</td><td>elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lytic-resistant RBCs</td><td>-</td></tr><tr><td>Reticulocytes</td><td></td><td></td><td>-</td><td>-</td></tr><tr><td colspan=2>Interfering substances: differential</td><td>platelet aggregates, erythroblasts, small lymphocytes, immature cells, resistant RBCs, giant or hypersegmented neutrophils, bands</td><td>fragile WBC, neutrophil aggregates, lytic-resistant RBCs, NRBCs, PLT clumps, cryofibrinogen, cryoglobulin, paraproteins</td><td>-</td></tr><tr><td>Throughput: max. CBCs per hour/Max. CBCs and dif Minimum specimen volume open/Closed/Sample de</td><td>ferentials per hour ad volume closed</td><td>40/40 21 μL/21 μL/500 μL</td><td>84/84 150 μL/230 μL/1.2 mL</td><td>CSFs: ~12/— 60 μL/—/—</td></tr><tr><td colspan=2>Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed</td><td>no no/—</td><td>no no/—</td><td> no/</td></tr><tr><td> Slide maker stainer sold separately or combined u </td><td>ınit</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Instrument archives patient data/Archiving is patien Maximum amount of archived data accessible wher</td><td>t specific 1 system online</td><td>yes/yes 300,000 on USB and 1,000 records with histograms on</td><td>yes/yes 10,000 results</td><td>yes/yes —</td></tr><tr><td>No. specimens for which numeric results saved in n</td><td>nemory at once</td><td>internal memory 300,000 on USB and 1,000 records with histograms on</td><td>10,000 results</td><td>>100,000 results</td></tr><tr><td>No. specimens for which histo/cytogram results sav</td><td>ed in memory at once</td><td>300,000 on USB and 1,000 records with histograms on internal memory</td><td>10,000 results</td><td>-</td></tr><tr><td>Instrument performs delta checks Parameters for which flags may appear</td><td></td><td>no dispersional data alerts, suspect parameter flags, and count invalidation flags</td><td>no NRBC, FWBC, NWBC, RRBC, band, IG, blast, variant lymph, RBC morph., DFLT, MCHC, LRI, URI, LURI,</td><td> control results out of range, expired reagents warning</td></tr><tr><td>Flagging is operator selectable</td><td></td><td>no</td><td>ATYPDEP, high-low interp. message, WBC yes</td><td>no</td></tr><tr><td>Tags and holds results for follow-up, confirmatory to Parameters for flags for holding samples defined by</td><td>esting, or rerun user or vendor</td><td>yes vendor</td><td>yes user</td><td>yes vendor</td></tr><tr><td>Histogram display: color with thresholds User interface can display choice of specimen or re</td><td>sult information</td><td>yes yes ves</td><td>yes ves</td><td>no ves</td></tr><tr><td>LIS interface formats supported Information transferred via LIS interface</td><td></td><td>proprietary numeric and flag results, instrument to LIS</td><td>proprietary numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—</td><td>RS232, bidirectional numeric and flag results, instrument to LIS; patient orders, LIS to instrument—broadcast</td></tr><tr><td colspan=2>LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test</td><td>no/no/no</td><td>broadcast; host query for patient demographics and orders no/no/no</td><td>yes/yes/—</td></tr><tr><td>Interface available or planned to automated specime Barcode symbologies read on specimen tube</td><td>en-handling system</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5, Chinese post, Code 39 Full ASCII, Code 93, EAN8, EAN13, EAN128, IATA, Industrial 2 of 5, Italian pharmaceutical, Matrix 2 of 5, MSI/ Plessey, UK/Plessey, Telepen, TriOptic, S-Code, UPC A, UPC E</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5, ISBT</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5, Data Matrix</td></tr><tr><td>Accommodates barcode placement per CLSI standa</td><td>rd Auto02-A2</td><td>no</td><td>no</td><td>yes</td></tr><tr><td>No. of cleaning or maintenance reagents required/ liquid reagents required</td><td>lo. of routine</td><td>1/2 daily: none: weekly: 15 minutes: quarterly: 10 minutes</td><td>1/3</td><td>0/2 (RBC and TNC reagents)</td></tr><tr><td>Onboard diagnostics for troubleshooting/Limited to Manufacturer can perform diagnostics via modem</td><td>software problems</td><td>uany, none, weekly. To minutes; quarterly: ~10 minutes no/no no</td><td>yes</td><td>yes/no no</td></tr><tr><td>Distinguishing features (supplied by company)</td><td></td><td>small: number of reagents used, footprint, sample size; safe, open tube sampling device; closed tube, continuous autoloading with automated rerun</td><td>touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode; rules- based result annotations</td><td>1 cell/µL limit of detection for RBC and TNC; consistent turnaround time for standarization and for Lean practices; disposable test cartridges eliminate carryover for infectious samples</td></tr><tr><td>does not include slide maker stainers</td><td></td><td></td><td></td><td></td></tr><tr><td colspan=2>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</td><td>*refer to CELL-DYN Emerald 22 Autoloader operator's manual for warnings, limitations, and precautions</td><td>*refer to CELL-DYN Ruby operator's manual for warnings, limitations, and precautions</td><td></td></tr></tbody></table>		

		REMATOLOGT ANA	LIZENJ	
Part 3 of 12		Beckman Coulter Eric Pabon epabon@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Eric Pabon epabon@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Eric Pabon epabon@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com
Name of instrument First year installed in U.S./Outside U.S./No. of No. units installed in U.S./Outside U.S./List	f units sold Sept. 2022–Aug. 2023 t price [†]	DxH Connected Workcell 2014/2014/— 100/200/\$690,000	DxH SMS II 2018/2018/>15 13/9/\$177,100	DxH 520 2019/2018/>300 >20/>700/\$30,000
Menu of chartable tests (standard menu: V MCHC, PLT, neut %&#, mono, lymph, eos	WBC, RBC, Hb, Hct, MCV, MCH, s, baso)	standard menu plus: IRF, MPV, MRV, NRBC %&#, RDW- CV, RDW-SD, automated retic #, retic %; body fluids: total nucleated count, RBC count for synovial, serous, CSE fluide, and elidemoking; MDW</td><td>_</td><td>standard menu plus: RDW, RDW-SD, MPV</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests Tests for research use only</td><td>s in development</td><td></td><td>Ξ</td><td> IMM %&#, LHD, MAF, PCT, PDW</td></tr><tr><td>Tests unique to analyzer</td><td></td><td>extended retic panel: MRV; direct count MPV, MCV, MDW; body fluid: BAL fluids; MDW</td><td>_</td><td>-</td></tr><tr><td>Differential method(s) used</td><td></td><td>biophysical characterization with 5 angles of light scatter for size and refractive capabilities, direct volume, conductivity for intracellular and nuclear complexity, more</td><td>_</td><td>optical bench with Coulter digital impedance</td></tr><tr><td>Analytical measurement range: • W • He • M</td><td>BC count/RBC count emoglobin/Platelet ICV (fL) or Hct (%)</td><td>0.050-400.000/0.005-8.500 0.10-25.50/3.0-3,000.0 50.00-150.00 (MCV) for measuring range, 0.00-85.00 (Hct) for operating range</td><td></td><td>$\begin{array}{l} 0.20-100.00\times10^3~\text{cells/}\mu\text{L}/0.20-8.00\times10^6~\text{cells/}\mu\text{L}\\ 0.20-25.00~\text{g/dL}/7.0-2000.0\times10^3~\text{cells/}\mu\text{L}\\ 50.0-150.0~\text{fL}~(\text{MCV}) \end{array}$</td></tr><tr><td>Precision: • WBC count/RBC count</td><td>euculocytes</td><td>≤3.0%/≤1.5%</td><td>_</td><td>$_$ ≤0.20 SD when 0.20–3.00 × 10³ cells/µL, ≤6.00% CV when >3.00 × 10³ cells/µL/≤3.00% CV @ 3.50–8.00 × 10⁶ cells/µL</td></tr><tr><td>Hemoglobin/Platelet MCV or Het</td><td></td><td>≤1.5%/≤3.5%</td><td>_</td><td>≤3% @ 11≤5 g/dL, ≤3% @ 5≤11 g/dL, ≤1.5% @ ≥11 g/dL/ ≤10.00% CV @ 100.0-200.0, ≤20.00% CV @ 7.00-100.0</td></tr><tr><td>Reticulocytes Accuracy of automated differential compa</td><td>ared with manual</td><td>=</math> neut= ±2.0; lymph, mono= ±3.0; eso, baso= ±1.0 or</td><td></td><td></td></tr><tr><td>differential (per CLSI H20-A2) Interfering substances: • WBC</td><td></td><td>10%, whichever is greater possibly precipitated elevated proteins, cryoglobulin, fragmented white cells, and triated white cells, byce-</td><td>none</td><td>is greater possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibringgen, PLT clumps, giant PLTs, applytingted</td></tr><tr><td>• RBC</td><td></td><td>resistant red cells, giant platelets, platelet clumps, more very high WBC count, high concentration of very large</td><td>none</td><td>white cells possibly agglutinated red cells, unlysed RBCs, elevated</td></tr><tr><td>MCV or Hct</td><td></td><td>very high WBC count, high concentration of very large platelets, autoagglutinins</td><td>none</td><td>wBCs, more possibly agglutinated red cells, unlysed RBCs, elevated WBCs, more</td></tr><tr><td>Platelet Hemoglobin</td><td></td><td>platelet clumps, white cell fragments, very small red cells, red cell fragments, giant platelets, electronic noise severe ligenia, benaria, certain unusual BBC</td><td>none</td><td>possibly giant PLTs, platelet clumps, microcytic RBCs, cryoglobulin, white or red cell fragments</td></tr><tr><td></td><td>I</td><td>abnormalities that resist lysing</td><td>lione</td><td>possibly lipids >o2.5 flig/dL (liperlia)</td></tr><tr><td colspan=2>Reticulocytes</td><td>-</td><td>_</td><td>-</td></tr><tr><td colspan=2>Interfering substances: differential</td><td>elevated triglycerides, precipitated elevated proteins, hypogranular granulocytes, agranular granulocytes, lyse- resistant red cells, very small or multipopulation lymphocytes</td><td>none</td><td>possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells</td></tr><tr><td>Throughput: max. CBCs per hour/Max. CBC</td><td>Cs and differentials per hour</td><td>300/300</td><td>140 slides/</td><td>55 closed-tube samples, 60 open-tube samples/</td></tr><tr><td>Minimum specimen volume open/Closed/S Microsample capability Instrument prepares microscope slides aut slide makers installed</td><td>Sample dead volume closed tomatically/No. of automatic</td><td>165 μL/165 μL/400 μL or 250 μL for MAP tubes yes yes/—</td><td>90 μL/90 μL/250–400 μL yes yes/—</td><td>16.7 μL/16.7 μL/1 mL standard tube or 375 μL MAP microtainer yes no/</td></tr><tr><td>Slide maker stainer sold separately or co</td><td>ombined unit</td><td>sold separately (\$165,000)</td><td>_</td><td>sold separately</td></tr><tr><td>Instrument archives patient data/Archiving Maximum amount of archived data access No. specimens for which numeric results s No. specimens for which histo/cytogram re</td><td>j is patient specific sible when system online saved in memory at once esults saved in memory at once</td><td>yes/yes up to 100,000 patient results including graphics up to 100,000 up to 100,000</td><td>no/no </td><td>yes/yes 30,000 patient results 30,000 patient results 30,000 patient results</td></tr><tr><td>Instrument performs delta checks Parameters for which flags may appear</td><td></td><td>yes P flag appears on slide with aspiration errors</td><td>no</td><td>— definitive range, measurement range, normal range, edited sample, low confidence result, H and H check fail, action limits, reference limits</td></tr><tr><td>Flagging is operator selectable Tags and holds results for follow-up, confin Parameters for flags for holding samples d Scattergram display: cell-specific color</td><td>rmatory testing, or rerun defined by user or vendor</td><td>yes yes user and vendor yes</td><td>no no</td><td>operator and vendor selectable yes user ves</td></tr><tr><td>Histogram display: color with thresholds User interface can display choice of speci</td><td>men or result information</td><td>yes yes</td><td>no yes</td><td>yes yes</td></tr><tr><td colspan=2>LIS interface formats supported Information transferred via LIS interface</td><td>ASTM 1394, ASTM 1238, IEEE MIB, CLSI LIS01-A2 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders (available with release of Workcell)</td><td>ASTM 1394, ASTM 1238, IEEE MIB, CLSI LIS1-A, CLSI LIS2-A patient demographics, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>IEEE MIB, CLSI LIS01-A2, CLSI LIS02-A2 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</td></tr><tr><td colspan=2>LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube</td><td>yes/yes/ Beckman Coulter Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7, ASTM</td><td>no/no/no Beckman Coulter Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5,</td><td>no/no/no no Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7,</td></tr><tr><td colspan=2>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>yes</td><td>NW7 yes</td><td>ISBT 128 (donor ID only) yes</td></tr><tr><td colspan=2>No. of cleaning or maintenance reagents required/No. of routine liquid reagents required Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems</td><td>1/4 daily: 30 minutes; weekly: none; monthly: none yes/no</td><td>1 preloaded cube with up to 30 cleaning cycles/3 (can vary): stain, buffer, diluent daily: up to 20 min.; weekly: up to 30 min.; monthly: as needed yes/no</td><td>1 preloaded bottle/2 (CBC, diff) daily: 5 min.; weekly: none; monthly: 15 min. yes/no</td></tr><tr><td>Distinguishing features (supplied by compa</td><td>any)</td><td>MDW aids in identifying severity of infection, risk of sepsis</td><td>DXH Concentrated ECO Diluent extends walkaway time,</td><td>small aspiration: 16.7 µL for a closed tube, 5-part</td></tr><tr><td>[†]does not include slide maker stainers Note: a dash in lieu of an answer means co question or question is not applicable</td><td>company did not answer</td><td>Workcell and DxH Slidemaker Stainer II are being designed to connect with Scopio X100HT digital cell morphology platform; ProCARE service program designed to prevent unplanned downtime, improve performance and reliability</td><td>Workcell and DxH Slidemaker Stainer II are being designed to connect with Scopio X100HT digital cell morphology platform</td><td>draws; small footprint: requires only 2 reagents for a full CBC-diff; reliable: less than 1 service call per year on average</td></tr></tbody></table>		

B CAP TODAY I OCTOBER 2023	HEMATOLOGY ANA	HEMATOLOGY ANALYZERS		
Part 4 of 12	Beckman Coulter Eric Pabon epabon@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Eric Pabon epabon@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Eric Pabon epabon@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	
Name of instrument First year installed in U.S./Outside U.S./No. of units sold Sept. 2022–Aug. 2 No. units installed in U.S./Outside U.S./List price [†]	DxH 560 AL 023 2020/2021/>150 45/142/\$52,000	DxH 690T 2019/2019/>150 0/10/\$218,000	DxH 900 2018/2018/>350 80/240/\$259,600	
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MC MCHC, PLT, neut %&#, mono, lymph, eos, baso)	H, standard menu plus: MPV, RDW-SD, RDW-CV	standard menu plus: retic and extended retic panel: retic %&#, MRV, IRF; extended platelet panel: MPV; extended RBC panel: NRBC %&#, RDW-CV, RDW-SD, more</td><td>standard menu plus: retic and extended retic panel: automated retic %&#, MRV, IRF; extended platelet panel: MPV; extended RBC panel: NRBC %&#, RDW-CV, RDW-SD; body fluids: total nucleated count</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests in development Tests for research use only</td><td> IMM %&#, LHD, MAF, PCT, PDW</td><td> body fluid mononuclear %&#, body fluid polymorphonuclear %&#, EGC %&#, high light scatter retic %&#; retic; RSf, LHD, UGC, MAF, MSCV oxtanded ratic papel: MBV: direct count MPV MCV</td><td>body fluid mononuclear %&#, body fluid polymorphonuclear %&#, EGC %&#, high light scatter retic %&#, retic; RSf, LHD, UGC, MAF, MSCV extended retic panel: MRV: direct count MPV MCV severity</td></tr><tr><td></td><td>_</td><td>severity of infection and risk of sepsis: MDW</td><td>of infection and risk of sepsis: MDW</td></tr><tr><td>Differential method(s) used</td><td>flow cytometry with proprietary dynamic gating</td><td>near-native biophysical cell characterization with 5 angles of light scatter for size and refractive capabilities, direct volume Coulter principle, more</td><td>near-native biophysical cell characterization with 5 angles of light scatter for size and refractive capabilities, direct volume Coulter principle, more</td></tr><tr><td>Analytical measurement range: • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes</td><td>0.20-100.00/.20-8.00 0.20-25.00/7.0-2000.0 50.0-150.0 (MCV), 0.0-85.0 (Hct) </td><td>$\begin{array}{l} 0.050-400.00\times10^3\ \text{cells/}\mu\text{L}/0.005-8.500\times10^6\ \text{cells/}\mu\text{L}\\ 0.10-25.50\ \text{g/dL}/3.0-3,000.0\times10^3\ \text{cells/}\mu\text{L}\\ 50.00-150.00\ \text{fL}\ (\text{MCV, direct measure})\\ 0.000-30.000 \end{array}$</td><td>$0.050-400.000\times10^3$ cells/µL/0.005–8.500$\times10^6$ cells/µL 0.10–25.50 g/dL/3.0–3,000.0$\times10^3$ cells/µL 50.00–150.00 fL 0.000–30.000</td></tr><tr><td>Precision: • WBC count/RBC count</td><td>\leq0.20 SD when 0.20–3.00×10³ cells/µL, \leq6.00% CV when >3.00×10³ cells/µL/\leq3.00% CV @ 3.50–8.00×10⁶ cells/µL/\leq0.20 SD when 0.20–3.00×10³ cells/µL, \leq6.00% CV when</td><td>≤3.0%/≤1.5%</td><td>≤3.0%/≤1.5%</td></tr><tr><td>Hemoglobin/Platelet</td><td>>3.00×10³ cells/µL/≤3.00% CV @ 3.50–8.00×10⁶ cells/µL ≤3% @ 11≤5 g/dL, ≤3% @ 5≤11 g/dL, ≤1.5% @ ≥11 g/ dL/≤10.00% CV @ 100.0–200.0, ≤20.00% CV @ 7.00– 100.0/≤3% @ 11≤5 g/dL, ≤3% @ 5≤11 g/dL, ≤1.5% @ ≥11</td><td>\leq1.5%/\leq3.5% @ 100.0–200.0 × 10³ cells/µL</td><td>≤1.5%/≤3.5%</td></tr><tr><td>MCV or Hct Reticulocytes</td><td>g/aL/≤10.00% 0v @100.0-200.0, ≤20.00% 0v @1.00-100.0 ≤1.0% (MCV) —</td><td>≤1.0% (MCV) <0.25 SD @ 0.00–2.00%, <0.70 SD @ 1.500–4.000%, <7% CV @ 4.000–15.000%</td><td>≤1.0% (MCV) </td></tr><tr><td>Accuracy of automated differential compared with manual differential (per CLSI H20-A2) Interfering substances: • WBC</td><td>NE, LY, MO ± 3.00; EO ± 1.5; BA ± 1.0 or 10%, whichever is greater possibly unlysed RBCs, NRBCs, cryoglobulin,</td><td>neut ±2.0; lymph, mono ±3.0; eso and baso ±1.0 or 10%, whichever is greater possibly precipitated elevated proteins, cryoglobulin,</td><td>neut= ± 2.0; lymph, mono= ± 3.0; eso, baso= ± 1.0 or 10%, whichever is greater possibly precipitated elevated proteins, cryoglobulin, frag-</td></tr><tr><td>• RBC</td><td>cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells possibly agglutinated red cells, unlysed RBCs, elevated</td><td>fragmented white cells, agglutinated white cells, lyse-resistant RBCs, giant PLTs, PLT clumps, unlysed particles >35 fL possibly very high WBC count, high concentration of</td><td>mented white cells, agglutinated white cells, lyse-resistant RBCs, giant PLTs, PLT clumps, unlysed particles >35 fL possibly very high WBC count, high concentration of very</td></tr><tr><td>• MCV or Het</td><td>WBCs, more</td><td>very large platelets, autoagglutinins</td><td>large platelets, autoagglutinins</td></tr><tr><td></td><td>WBCs, more</td><td>very large platelets, autoagglutinins</td><td>large platelets, autoagglutinins</td></tr><tr><td>Platelet</td><td>possibly giant PLIs, platelet clumps, microcytic HBCs, cryoglobulin, white or red cell fragments</td><td>possibly platelet clumps, white cell fragments, very small red cells, red cell fragments, giant platelets, electronic noise</td><td>possibly platelet clumps, white cell tragments, very small red cells, red cell fragments, giant platelets, electronic noise</td></tr><tr><td>Hemoglobin Reticulocytes</td><td>possibly lipids >62.5 mg/dL (lipemia)</td><td>possibly severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing erythrocyte inclusions stained by new methylene blue, if</td><td>possibly severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing —</td></tr><tr><td>Interfering substances: differential</td><td>possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells</td><td>sufficiently numerous within a sample, more elevated triglycerides, precipitated elevated proteins, hypogranular granulocytes, agranular granulocytes, more</td><td>elevated triglycerides, precipitated elevated proteins, hypo- granular granulocytes, agranular granulocytes, lyse-resistant</td></tr><tr><td>Throughput: max. CBCs per hour/Max. CBCs and differentials per hour</td><td>55 closed-tube samples, 60 open-tube samples/ 55 closed-tube samples. 60 open-tube samples</td><td>100/100</td><td>300 samples/300 samples</td></tr><tr><td>Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic</td><td>16.7 µL/16.7 µL/1 mL standard tube or 375 µL MAP microtainer yes no/</td><td>165 µL/165 µL/400 µL or 250 µL with MAP tubes yes no/—</td><td>165 µL/165 µL/250–400 µL yes по/—</td></tr><tr><td>slide makers installed Slide maker stainer sold separately or combined unit</td><td>sold separately</td><td>sold separately (\$165,000) or combined</td><td>_</td></tr><tr><td>Instrument archives patient data/Archiving is patient specific</td><td>yes/yes 20.000 potient results</td><td>yes/yes</td><td>yes/yes</td></tr><tr><td>No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at o Instrument performs delta checks</td><td>30,000 patient results nce 30,000 patient results no</td><td>up to 60,000 patient results up to 60,000 patient results ves</td><td>up to 100,000 patient results including graphics up to 100,000 patient results including graphics ves</td></tr><tr><td>Parameters for which flags may appear Flagging is operator selectable</td><td>definitive range, measurement range, normal range, edited sample, low confidence result, H and H check fail, action limits, reference limits operator and vendor selectable</td><td>suspect messages: Abn hemoglobin, cellular inter, dimorphic reds, giant platelets, imm grans, left shift, LY blast, MO blast, NE blast, NRBC, RBC frag/micro, more operator and vendor selectable</td><td>yes</td></tr><tr><td>Parameters for flags for holding samples defined by user or vendor Scattergram display: cell-specific color Histogram display: color with thresholds</td><td>yes user yes yes</td><td>yes user yes (3D scatter and surface plots for flow modules) yes</td><td>yes user and vendor yes (WBC, nRBC, reticulocyte) yes (WBC, RBC, PLT)</td></tr><tr><td>User interface can display choice of specimen or result information LIS interface formats supported</td><td>yes IEEE MIB. CLSI LIS01-A2, CLSI LIS02-A2</td><td>yes ASTM 1394-91, ASTM 1238-95, IEEE MIB, CLSI LIS01-A2</td><td>yes CLSI LIS01-A2</td></tr><tr><td>Information transferred via LIS interface</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders</td></tr><tr><td>LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test Interface available or planned to automated specimen-handling syster Barcode symbologies read on specimen tube</td><td>no/no/no n Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7, ISBT 128 (donor ID only)</td><td>yes/yes/yes Beckman Coulter, Roche Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5,</td><td>yes/yes/yes Beckman Coulter Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5,</td></tr><tr><td>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>No. of cleaning or maintenance reagents required/No. of routine liquid reagents required Time required for daily, weekly, monthly maintenance</td><td>1 preloaded bottle/2 (CBC, diff) daily: 5 min.; weekly: none; monthly: 15 min.</td><td>1 preloaded cube with up to 30 cleaning cycles/3 (CBC, diff, retic [optional]) daily: none (autonomous); weekly: none; monthly: none</td><td>1 preloaded cube with up to 30 cleaning cycles/3 (CBC/ diff incl. Coulter Plt, retic, extended retic panel)</td></tr><tr><td>Onboard diagnostics for troubleshooting/Limited to software problems Manufacturer can perform diagnostics via modem</td><td>yes/no no</td><td>yes/no yes</td><td>yes/no yes</td></tr><tr><td>Distinguishing features (supplied by company) [†]does not include slide maker stainers Note: a dash in lieu of an answer means company did not answer question or question is not applicable</td><td>small aspiration: 16.7 μL for a closed tube, 5-part differential instrument, ideal for infants and difficult draws; 50 tube load and walkaway capacity; integrated touchscreen and only one external reagent</td><td>delivers accurate, first-analysis results through VCS technology; MDW aids in identifying severity of infection, risk of sepsis as part of CBC-diff for ED patients; allows standardization across hospital and IDN networks</td><td>DataFusion uses real-time analytics and bypasses special modes, avoiding reruns; platelets achieve industry-leading accuracy, precision, and low backgrounds with first-pass technology; near-native state RBC analysis throughout the maturation cycle for direct read and accurate indices</td></tr></tbody></table>		

		HEMATOLOGY ANA	LYZERS	UCIUDER 2023 I CAPIUDAT 49
Part 5 of 12		CellaVision Scott Dunbar scott.dunbar@cellavision.com Durham, NC	CellaVision Scott Dunbar scott.dunbar@cellavision.com Durham, NC	Diatron MI Frank Matuszak frank.matuszak@diatron.com Medley, FL
		919-806-4420 www.cellavision.com	919-806-4420 www.cellavision.com	833-228-7931 www.diatron.com
Name of instrument First year installed in U.S./Outside U.S./No. of units so No. units installed in U.S./Outside U.S./List price [†]	ld Sept. 2022–Aug. 2023	CellaVision DC-1 2021/2019/ 	CellaVision DM9600/DM1200 2004/2003/ //~\$135,000-\$175,000	Abacus 3CP 2013/2013/ 56/1,039/\$20,385
Menu of chartable tests (standard menu: WBC, RE MCHC, PLT, neut %&#, mono, lymph, eos, baso)	3C, Hb, Hct, MCV, MCH,	mono, lymph, eos, baso; WBCs: seg, band, baso, eos, mono, lymph, promyelo, myelo, metamyelo, blast, lymph variant form, NRBC, giant PLT, PLT clumps; RBCs: polychromatic cells, hypochromatic cells, anisocytosis, microcytosis, macrocytosis, poikilocytosis; PLT: PLT estimate	neut %&#, mono, lymph, eos, baso, segmented, bands, blast, promyelocytes, myelocytes, metamyelocytes, variant lymphocytes, plasma cells, giant platelets, platelet clumps, erythroblasts, more</td><td>WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, mono, lymph, RDW%, MPV, GRA %&#</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests in deve Tests for research use only Tests unique to analyzer</td><td>lopment</td><td></td><td>analysis of cytocentrifuged samples, body fluids (reported parameters: neutrophils, eosinophils, lymphocytes, macrophages, including monocytes), other (basophils,</td><td></td></tr><tr><td>Differential method(s) used</td><td></td><td>automated brightfield microscopy, image analysis, Al</td><td>light microscopy, image analysis, artificial neural</td><td>volumetric impedance method, light absorbance for</td></tr><tr><td>Analytical macaurament ranges</td><td>t/DDC count</td><td></td><td>networks</td><td></td></tr><tr><td>Hemoglob</td><td>in/Platelet</td><td>_</td><td>_</td><td>0.95-63.45/0.44-7.74 1.4-23.7/11-975</td></tr><tr><td>• MCV (fL) c</td><td>or Hct (%)</td><td>-</td><td>-</td><td>-</td></tr><tr><td>Reticulocy</td><td>/tes</td><td>_</td><td>—</td><td>-</td></tr><tr><td>Precision: • WBC count/RBC count • Hemoglobin/Platelet</td><td></td><td>_</td><td>_</td><td><2.7%/<1.7%</td></tr><tr><td>MCV or Hct</td><td></td><td>_</td><td>_</td><td><1.7% (MCV and Hct)</td></tr><tr><td>Reticulocytes</td><td></td><td>—</td><td>—</td><td>-</td></tr><tr><td>Accuracy of automated differential compared with differential (per CLSI H20-A2)</td><td>n manual</td><td>seg neu% y = $0.9904x + 0.37$; lymph% y = $0.998x + 0.12$; mono% y = $0.9983x + 0.24$; eos% y = $0.9912x + 0.03$; baso% y = $0.9427 + 0.08$</td><td>seg neut% y=0.97x+1.3, r= 0.987; lymph% y=0.97x +1.2, r= 0.979; eos% y=1.01+0.1, r=0.960; mono% y=0.97+0.2, r=0.941; band neut% y=0.87x+0.1, r=0.917</td><td>_</td></tr><tr><td>Interfering substances: • WBC</td><td></td><td>-</td><td>_</td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td></tr><tr><td>RBC MCV or List</td><td></td><td>-</td><td>-</td><td>WBC count > $50.0 \times 10^{3}/\mu$L</td></tr><tr><td>Platelet</td><td></td><td>_</td><td>_</td><td>PLT clumps/large PLTs</td></tr><tr><td>Hemoglobin</td><td></td><td>_</td><td>_</td><td>WBC count $>50.0 \times 10^3/\mu$L, lipids >270 mg/dL</td></tr><tr><td>Reticulocytes</td><td></td><td>-</td><td>_</td><td>-</td></tr><tr><td>Interfering substances: differential</td><td></td><td>-</td><td>-</td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td></tr><tr><td colspan=2>Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed</td><td>—/10 slides —</td><td>—/35 differentials —</td><td>60/60 100 µL/100 µL/</td></tr><tr><td>Instrument prepares microscope slides automatica slide makers installed</td><td>ally/No. of automatic</td><td> no/</td><td>_</td><td>no/</td></tr><tr><td>Slide maker stainer sold separately or combined</td><td>lunit</td><td>sold separately</td><td>—</td><td>—</td></tr><tr><td>Instrument archives patient data/Archiving is patie Maximum amount of archived data accessible who No. specimens for which numeric results saved in No. specimens for which histo/cytogram results sa</td><td>nt specific en system online memory at once aved in memory at once</td><td>yes/no unlimited 1,500</td><td>yes/no unlimited ~4,000</td><td>yes/no 10,000 results 10,000 results 10,000 results</td></tr><tr><td>Instrument performs delta checks Parameters for which flags may appear</td><td></td><td>no </td><td>no </td><td>no range flags, measurement condition flags, parameter warning, error flags</td></tr><tr><td>Flagging is operator selectable</td><td>tacting or rorun</td><td></td><td>-</td><td>no</td></tr><tr><td>Parameters for flags for holding samples defined to Scattergram display: cell-specific color</td><td>by user or vendor</td><td>yes — yes, can be imported from the LIS and displayed in the</td><td>_</td><td>vendor no</td></tr><tr><td>Histogram display: color with thresholds</td><td></td><td>user interface —</td><td>_</td><td>yes</td></tr><tr><td>User interface can display choice of specimen or</td><td>result information</td><td>yes</td><td>_</td><td>no</td></tr><tr><td>LIS interface formats supported Information transferred via LIS interface</td><td></td><td>ASTM 1394-91 numeric and flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>ASTM 1394 numeric and flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host guery for patient demographics and orders</td><td>HL/, Diatron Serial Communication numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</td></tr><tr><td colspan=2>LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test Interface available or planned to automated specimen-handling system</td><td>no/no/no no Codabar Cada 20, Cada 128, Interlaaved 2 of 5</td><td>no/no/yes (for peripheral blood)</td><td>no/no/no no Codabar Coda 20, Coda 128, Interlaqued 2 of 5</td></tr><tr><td colspan=2></td><td>DataMatrix, QR</td><td>DataMatrix</td><td></td></tr><tr><td colspan=2>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>no</td><td>-</td><td>no</td></tr><tr><td>No. of cleaning or maintenance reagents required</td><td>/No. of routine</td><td>0/0</td><td>none/1</td><td>1/3</td></tr><tr><td colspan=2>Time required for daily, weekly, monthly maintenance</td><td>daily: none; weekly: 5 min.</td><td>daily: none; weekly: 5 minutes</td><td>daily: 10 minutes; weekly: 15 minutes; monthly: 10 minutes</td></tr><tr><td>Onboard diagnostics for troubleshooting/Limited to Manufacturer can perform diagnostics via modem</td><td>o software problems</td><td>yes/no no</td><td>yes/no no</td><td>no/no no</td></tr><tr><td>Distinguishing features (supplied by company)</td><td></td><td>network use allows remote review of blood smears and linking of multiple CellaVision analyzers in multiple locations; WBC and other nucleated cells classified into 18 categories; RBC morphology characterized for 6 categories; leverages high-speed robotics and digital imaging to automatically locate and capture high-quality images of cells</td><td>fully automated slide handling and oiling available in 2 models; performs peripheral blood and body fluid differentials; WBC and other nucleated cells classified into 18 categories; RBC morphology characterized for 22 categories; network use allows remote review of blood smears and linking of multiple analyzers in multiple locations</td><td>reliable 3-part diff analyzers with 2 sampling modes (cap-piercing mode for closed-tube sampling and another for open tubes); operator safety: self-cleaning procedures minimize daily maintenance; user-friendly, easy-to-operate, high-resolution touchscreen; USB and barcode option to load QC target values; capable of reading QR codes for reference input data; confidence: system uses easy-to-understand warning messages and sample flags, employs a comprehensive QC SW package</td></tr></tbody></table>	

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

50 CAP TODAY OCTOBER 2023			HEMATOLOGY ANA		
Part 6 of 12			Diatron MI Frank Matuszak frank.matuszak@diatron.com Medley, FL 833-228-7931 www.diatron.com	HORIBA Medical Susan Behnke susan.behnke@horiba.com Irvine, CA 888-903-5001 ext. 4553 www.horiba.com/us/en/medical	HORIBA Medical Susan Behnke susan.behnke@horiba.com Irvine, CA 888-903-5001 ext. 4553 www.horiba.com/us/en/medical
Name of instrument First year installed in U.S. No. units installed in U.S.	/Outside U.S S /Outside U	./No. of units sold Sept. 2022–Aug. 2023 S /l ist price [†]	Abacus 5 2013/2009/— 35/3 120/\$31 850	Pentra 60C+ Hematology Analyzer 2000/2000/	Pentra XL 80 2004/2003/
Menu of chartable tests MCHC, PLT, neut %&#	; (standard r ; mono, lym	nenu: WBC, RBC, Hb, Hct, MCV, MCH, ph, eos, baso)	standard menu plus: RDW-SD, RDW-CV, MPV	standard menu plus: RDW, MPV	standard menu plus: automatic dilution of over-range results (WBC × 3, RBC/Hgb/PLT × 2), RDW, MPV
Tests submitted for 510 Tests for research use of Tests unique to analyze	(k) clearanc only r	e/Tests in development	_ _ _	 PCT, PDW, ATL, LIC 	— PCT, PDW, ATL, LIC automatic dilution protocol
Differential method(s) u	sed		laser light scatter technology, impedance method, light absorbance	DHSS technology combining cytochemistry, focused flow impedance, light absorbance principles of measurement	DHSS technology combining cytochemistry, focused flow impedance, light absorbance
Analytical measuremen	t range:	WBC count/RBC count	0.2–100/0.36–7.19	0–120/0–8	0–120/0–8
		Hemoglobin/Platelet	1.1–22.2/15–2,000	0-24/0-1,900	0-24/0-1,900 (>2 g/dL Hb)
		MCV (fL) or Hct (%) Reticulocytes	-	0–67% (Hct) —	0–2,800 (<2 g/dL Hb), 0–67% (Hct) —
Precision: • WBC co	ount/RBC co	unt	<2.7%/<1.7%	<2%/<2%	<2%/<2%
Hemog	lobin/Platele	it	<2.0%/<6%	<1%/<5%	<1%/<5%
Kicv or Reticul	nct ocytes		< 1.7% (MUV and HCt) —	<2% (HCT) —	<2% (HCI) —
Accuracy of automated differential (per CLSI	differential H20-A2)	compared with manual	-	neut% r=0.99, lymph% r=0.98, mono% r=0.96, eos% r=0.89, baso% r=0.54	neut% r=0.99, lymph% r=0.98, mono% r=0.96, eos% r=0.89, baso% r=0.54
Interfering substances:	• WBC		>5 NRBCs/100 WBCs, PLT clumps, large PLTs	NRBCs, PLT clumps, lyse-resistant RBCs	NRBCs, PLT clumps, lyse-resistant RBCs
	KBC	or Hot	WBC count >75.0 \times 10 ³ /µL	Cold agglutinins	Cold agglutinins
	Plate	let	PIT clumps/large PITs	microcytes. PIT clumps	microcytes. PLT clumps
	• Hem	oglobin	WBC count >75.0 \times 10 ³ /µL, lipids >280 mg/dL	extreme lipemia, leukocytosis	extreme lipemia, leukocytosis
	 Retic 	ulocytes	-	_	-
Interfering substances:	differential		>5 NRBCs/100 WBCs, PLT clumps, large PLTs	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed		ax. CBCs and differentials per hour losed/Sample dead volume closed	60/60 110 μL/110 μL/—	60/60 30 μL for CBC, 53 μL for CBC and differential/30 μL for CBC and 53 μL for CBC and differential/—	80/80 30 μL for CBC/53 μL for CBC and differential/0.5 mL
Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed		des automatically/No. of automatic	no no/—	yes no/—	yes no/—
Slide maker stainer se	old separate	ly or combined unit	—	—	—
Instrument archives pat Maximum amount of ar No. specimens for whic No. specimens for whic	ient data/Ar chived data h numeric re h histo/cytoo	chiving is patient specific accessible when system online esults saved in memory at once tram results saved in memory at once	yes/no 100,000 results 100,000 results 100,000 results	yes/yes 10,000 sample results with graphics and numerical data unlimited with backup unlimited with backup	yes/yes 10,000 sample results with graphics and numerical data unlimited with backup unlimited with backup
Instrument performs de Parameters for which fl	lta checks ags may app	pear	no pathological flags, lab limits (normal ranges), reagents alert, instrument alerts	no all CBC and diff parameters have flags	yes all CBC and diff parameters have flags
Flagging is operator sel Tags and holds results 1 Parameters for flags for	ectable for follow-up holding san	, confirmatory testing, or rerun nples defined by user or vendor	no yes vendor	no yes vendor	no yes vendor
Scattergram display: ce Histogram display: color	II-specific co with thresh	olor Iolds	yes yes	yes yes	yes yes
User interface can disp	ay choice of	f specimen or result information	no		no
LIS interface formats su Information transferred	pported via LIS inter	face	HL7, Diatron Serial Protocol histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	ASTM 1394 and 1238, HL7 numeric and flag results, histograms and scatter- plots, instrument to LIS; patient demographics, LIS to instrument—broadcast	proprietary, ASTM 1394 and 1238, HL7 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test		sults/Sent in message to LIS/ responding LOINC for each test	no/no/no	no/no/no	no/no/no
Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube Accommodates barcode placement per CLSI standard Auto02-A2		men tube per CLSI standard Auto02-A2	Codabar, Code 39, Code 128, Interleaved 2 of 5 yes	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5 yes	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5 yes
No. of cleaning or main liquid reagents requi	tenance rea red	gents required/No. of routine	1/3	2/5	2/5
time required for daily,	weekly, mo	ntniy maintenance	dally: 10 minutes; weekly: 15 minutes; monthly: 10 minutes	dally: 10 minutes; weekly: 15 minutes; monthly: 15 minutes	dally: 10 minutes; weekly: 15 minutes; monthly: 15 minutes
Onboard diagnostics for Manufacturer can perfo	rtroubleshoo rm diagnost	pting/Limited to software problems ics via modem	no/no no	yes/yes yes, with Data Manager	no/yes no
Manufacturer can perform diagnostics via modem Distinguishing features (supplied by company)		company)	compact, benchtop 5-part laser WBC differential analyzer provides accurate and precise results; 2 sampling modes (cap-piercing mode for closed-tube sampling and another for open tubes); field upgradeable with optional autosampler with built-in barcode reader; sample capacity: 100 tubes; user friendly and easy to operate: easy-to-follow, intuitive icon user interface	reliable 5-part WBC differential technology; mean time between failures more than 200 days; small footprint; small sample size of 53 μ L; can connect to Lite ^{DM} Patient Data Manager, which interfaces with third-party medical devices	compact 5-part differential instrument with autoloader and autodilution capability, auto rerun feature, autovalidation; can connect to Lite ^{DM} Patient Data Manager, which interfaces with third-party medical devices

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

Part 7 of 12		Mindray Anna Chen a.chen@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com	Mindray Anna Chen a.chen@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com	PixCell Medical Ryan Venturi info@pixcell-medical.com Longmont, CO 888-615-4122 www.pixcell-medical.com	
Name of instrument First year installed in U.S./Outside U.S. No. units installed in U.S./Outside L	S./No. of units sold Sept. 2022–Aug. 2023 J.S./List price†	BC-5390 2016/2012/— 24/1,612/—	BC-3600 2015/2011/— 78/4,120/—	HemoScreen 2018/2016/ 	
Menu of chartable tests (standard MCHC, PLT, neut %&#, mono, lyn Tests submitted for 510(k) clearand Tests for research use only Tests unique to analyzer	menu: WBC, RBC, Hb, Hct, MCV, MCH, nph, eos, baso) :e/Tests in development	standard menu plus: RDW-CV, RDW-SD, MPV, mono %&#, lymph %&#, eos %&#, baso %&# — — —</td><td>WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, gran %&#, lymph %&#, mid %&#, MPV, RDW none/none none none</td><td>standard menu plus: MPV, RDW </td></tr><tr><td>Differential method(s) used</td><td></td><td>flow cytometry, light scatter</td><td>impedance method for WBC, RBC, MCV, RDW, PLT, MPV and WBC 3-part differential determination, colorimetric</td><td>digital microscopy and computer-vision algorithms</td></tr><tr><td>Analytical measurement range:</td><td> WBC count/RBC count Hemoglobin/Platelet MCV (fL) or Hct (%) Reticulocytes </td><td>0.3–200/0.2–8.0 0.5–25/5–2,000 2–75% (Hct)</td><td>method for HGB determination 0.3–99.9/0.20–7.99 1.0–24.9/10–999 —</td><td>0.5–80.0 × 10³/μL/1.0–8.8 × 10⁶/μL 3.0–25.0 g/dL/20–800 × 10³ /μL 9.0–78.0% (Hct) —</td></tr><tr><td>Precision: • WBC count/RBC co</td><td>punt</td><td><0.15 (SD) or 3.0% (CV)/<1.5%</td><td>WBC ≥4.0: ≤3.0% CV%; 1.0 ≤WBC ≤2.0: ≤7.0% CV%/ ≤2.5% CV%</td><td>4.0%/1.5%</td></tr><tr><td>Hemoglobin/Platel</td><td>et</td><td><1.5%/<7.5 (SD) or 5% (CV)</td><td>≤2.0% CV%/PLT ≥150: ≤6.0% CV%; 20 ≤PLT≤ 50: ≤20.0% CV%</td><td>1.6%/3.5%</td></tr><tr><td>MCV or HctReticulocytes</td><td></td><td><1.5% (MCV)</td><td>≤2.0 CV% (MCV), ≤2.5% CV% (Hct) —</td><td>1.6% (Hct) —</td></tr><tr><td>Accuracy of automated differential differential (per CLSI H20-A2)</td><td>compared with manual</td><td>neu%: ±5.00 or ±10.0%; lym%: ±4.00 or ±10.0%; mon%: ±3.00 or ±10.0%; eos%: ±2.00 or ±10.0%; bas%: ±1.00 or ±10.0%</td><td>_</td><td>_</td></tr><tr><td>Interfering substances: • WBC</td><td>)</td><td>platelet aggregation, lyse-resistant erythrocytes, erythroblasts, cold agglutinin, cryoglobulin, giant platelets, lipemia, chylomicronemia</td><td>certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, unlysed particles, very large or aggregated platelets</td><td>no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides</td></tr><tr><td>• RBC</td><td></td><td>cold agglutinin, fragmented erythrocytes, leukocytosis, giant platelets</td><td>very high WBC count, high concentration of very large platelets, agglutinated RBCs and smaller RBC</td><td>no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides</td></tr><tr><td>• MCV</td><td>/ or Hct</td><td>RBC fragments, very high WBC count, high concentration of very large platelets, microclots, RBC rouleaux or applications (autoapplutingtion)</td><td>very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments</td><td>no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides</td></tr><tr><td>• Plate</td><td>elet</td><td>PLT aggregation or PLT satellitism, giant platelets, microcytosis, fragmented erythrocytes</td><td>very small red blood cells near the upper PLT threshold, cell fragments, clumped platelets as with oxalate or heparin, platelet fragments or cellular debris near the lower platelet threshold</td><td>no significant interference up to 30 mg/dL bilirubin, 729 mg/dL triglycerides</td></tr><tr><td>• Hem</td><td>noglobin</td><td>leukocytosis, lipemia, chylomicronemia, abnormal protein</td><td>very high WBC count, severe lipemia, certain unusual RBC abnormalities that resist lysing, anything that increases the turbidity of the sample such as elevated levels of triglycerides</td><td>no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides</td></tr><tr><td>• Reti</td><td>culocytes</td><td>-</td><td>-</td><td>-</td></tr><tr><td>Interfering substances: differential</td><td></td><td>lysis-resistant RBC, NRBC, PLT aggregates, giant PLT</td><td>known factors that affect the WBC count as listed above, high triglycerides that can affect lysing</td><td>-</td></tr><tr><td colspan=2>Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed</td><td>60/60 100 μL/33 μL, predilute 20 μL/1 mL yes no/—</td><td>60/60 100 μL/21 μL, predilute 20 μL/1 mL yes no/—</td><td>20/10 40 μL/40 μL/— yes no/—</td></tr><tr><td>Slide maker stainer sold separate</td><td>ely or combined unit</td><td>—</td><td>-</td><td>-</td></tr><tr><td colspan=2>Instrument archives patient data/Archiving is patient specific Maximum amount of archived data accessible when system online No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at once</td><td>yes/yes 100,000 results 100,000 100,000 ves</td><td>no/no 40,000 results 40,000 40,000 no</td><td>yes/no 1,000 1,000 —</td></tr><tr><td>Parameters for which flags may ap Flagging is operator selectable</td><td>pear</td><td>immature gran? Abn/atypical lym? RBC agglutination? iron deficiency? PLT clump? NRBC? blasts? RBC lyse resist? leukocytosis, leukopenia, anemia, anisocytosis, more operator and vendor selectable</td><td>no</td><td>all CBC and differential parameters have flags; pathological flags, range flags, measurement condition flags, parameter warning, error flags no</td></tr><tr><td>Tags and holds results for follow-up Parameters for flags for holding sat Scattergram display: cell-specific c</td><td>p, confirmatory testing, or rerun mples defined by user or vendor :olor</td><td>yes — yes</td><td>no no</td><td>no vendor no</td></tr><tr><td>Histogram display: color with thresh User interface can display choice of</td><td>holds of specimen or result information</td><td>yes yes</td><td>yes no</td><td>no yes</td></tr><tr><td>LIS interface formats supported Information transferred via LIS inte</td><td>rface</td><td>HL7 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>HL7 numeric and flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</td><td>HL7, POCT-1A numeric and flag results, instrument to LIS; host query for patient demographics and orders</td></tr><tr><td>LOINC codes transmitted with all re Listing of machine codes and cor</td><td>esults/Sent in message to LIS/ responding LOINC for each test</td><td>yes/yes/yes</td><td>yes/yes/no</td><td>yes/yes/yes</td></tr><tr><td>Interface available or planned to au Barcode symbologies read on spec</td><td>itomated specimen-handling system imen tube</td><td>none Codabar, Code 39, Code 93, Code 128, Interleaved 2 of 5, UPC/EAN</td><td>Codabar, Code 39, Code 128</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5</td></tr><tr><td>Accommodates barcode placement</td><td>t per CLSI standard Auto02-A2</td><td>—</td><td>_</td><td></td></tr><tr><td>No. of cleaning or maintenance rea liquid reagents required Time required for daily, weekly, mo Onboard diagnostics for troublesho Manufacturer can berform diagnos</td><td>agents required/No. of routine onthly maintenance oting/Limited to software problems tics via modem</td><td>1/4 daily: <10 minutes yes/no ves</td><td>1/4 daily: <10 minutes yes/no no</td><td>0/0 none yes/no yes</td></tr><tr><td>Distinguishing features (supplied b</td><td>y company)</td><td>60 QC files; maximum 40 samples autoloader capacity.</td><td>10.4-inch all-in-one Glance color touchscreen, touch-</td><td>cartridge-based 5-part differential CBC analyzer FDA</td></tr><tr><td colspan=2>Distinguishing features (supplied by company) [†]does not include slide maker stainers Note: a dash in lieu of an answer means company did not answer question or question is not applicable</td><td>sample adaptors for pediatric and predilution samples; operation software with built-in data-management functions, 3 modes of operation: autoloader and opened and closed tube; customizable patient reports; only 1 maintenance reagent</td><td>button maintenance procedures, and low sample requirement; 40,000 patient results storage, close-tube sampling, open-tube sampling for pediatric samples; 3 types of sample adaptors, barcoded reagent, and 5 minutes daily start-up and maintenance</td><td>cleared for POC use; easy to use–no calibration, reagent handling, or routine maintenance required; lab-quality results obtained within 5 minutes from a drop of venous or capillary blood</td></tr></tbody></table>			

HEMATOLOGY ANALYZERS

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52 CAP TODAY I OCTOBER 2023				HEMATOLOGY ANALYZERS		
Part 8 of 12				Scopio Labs Lianne Trantz lianne.trantz@scopiolabs.com Tel Aviv, Israel +972 50-272-7929 scopiolabs.com	Siemens Healthineers Sheryl Kirk sheryl.kirk@siemens-healthineers.com Tarrytown, NY 469-390-7319 siemens-healthineers.com/hematology	Siemens Healthineers Sheryl Kirk sheryl.kirk@siemens-healthineers.com Tarrytown, NY 469-390-7319 siemens-healthineers.com/hematology
Name of instrumen	nt			X100 / X100HT with Full-Field Peripheral Blood Smear	Advia 360 Hematology System	Advia 560/560AL Hematology System
First year installed in No. units installed i	n U.S./Outs in U.S./Ou	ide U.S./N tside U.S	lo. of units sold Sept. 2022–Aug. 2023 ./List price [†]	(PBS) Application 	2015/2015/	2015/2015/— —
Menu of chartable MCHC, PLT, neut	tests (star %&#, mo	ndard me no, lympł	ınu: WBC, RBC, Hb, Hct, MCV, MCH, ı, eos, baso)	mono, lymph, eos, baso, WBC: seg, band, promyelo, myelo, metamyelo, blast, atypical lymph, abbarent lymph, large granular lymph, plasma cells, NRBC; PLT: estimate	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, lymph, MID, GRA, MID%, GRA%, MPV, RDW-CV	WBC, RBC, Hb, Hct, MCV, MCH, PLT, neut %&#, mono, lymph, eos, baso</td></tr><tr><td>Tests submitted for Tests for research ı</td><td>r 510(k) cl use only</td><td>earance/1</td><td>Fests in development</td><td> X100 / X100HT with full-field bone marrow aspirate (BMA) application</td><td></td><td>=</td></tr><tr><td>Tests unique to ana</td><td>alyzer</td><td></td><td></td><td></td><td>_</td><td>—</td></tr><tr><td>Differential method</td><td>l(s) used</td><td></td><td></td><td>computational photography, image analysis, artificial intelligence</td><td>volumetric impedance change for WBC, RBC, PLT; lytic reagents with impedance method for 3 subpopulations; spectrophotometry for HGB</td><td>volumetric impedance change for WBC, RBC, PLT; light scattering baso measurement; light scattering 4-diff mea- surement LYM, MON, NEU, EOS; spectrophotometry for HGB</td></tr><tr><td>Analytical measure</td><td>ement ran</td><td>ge:</td><td>WBC count/RBC count</td><td>—</td><td>0.0-85.0/0.00-8.00</td><td>0.20-100.0/0.36-7.19</td></tr><tr><td></td><td></td><td></td><td>Hemoglobin/Platelet</td><td>-</td><td>0.0-25.0/0-1,000</td><td>1.10-22.2/15.0-1,000</td></tr><tr><td></td><td></td><td></td><td>• MCV (fL) or Hct (%)</td><td>-</td><td>50–120 (MCV)</td><td>50–120 (MCV)</td></tr><tr><td></td><td></td><td></td><td>Reticulocytes</td><td>-</td><td>—</td><td>-</td></tr><tr><td>Precision: • WE</td><td>BC count/I</td><td>RBC coun</td><td>ıt</td><td>-</td><td><4.0%/<2.5%</td><td><3.4%/<2.0%</td></tr><tr><td>• He</td><td>emoglobin</td><td>/Platelet</td><td></td><td>-</td><td><2.4%/<7.0%</td><td><2.4%/<7.0%</td></tr><tr><td>• M(</td><td>CV or Hct</td><td></td><td></td><td>-</td><td><2.0% (MCV)</td><td><2.0% (MCV)</td></tr><tr><td>• Re</td><td>eticulocyte</td><td>s</td><td></td><td>-</td><td>_</td><td>-</td></tr><tr><td>Accuracy of automa differential (per C</td><td>ated diffe</td><td>rential co A2)</td><td>mpared with manual</td><td>_</td><td>_</td><td>-</td></tr><tr><td>Interfering substand</td><td>ices:</td><td>• WBC</td><td></td><td>-</td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td></tr><tr><td></td><td></td><td>• RBC</td><td></td><td>-</td><td>WBC count >75.0 \times 103/µL</td><td>WBC count $>75.0 \times 103/\mu L$</td></tr><tr><td></td><td></td><td> MCV or </td><td>Hct</td><td>-</td><td>WBC count >75.0 \times 103/µL</td><td>WBC count >75.0 \times 103/µL</td></tr><tr><td></td><td></td><td> Platelef </td><td>t</td><td>-</td><td>PLT clumps, large PLTs</td><td>PLT clumps, large PLTs</td></tr><tr><td></td><td></td><td>• Hemog</td><td>lobin</td><td>_</td><td>WBC count >75.0 \times 103/µL, lipids >280 mg/dL</td><td>WBC count >75.0 × 103/µL, lipids >280 mg/dL</td></tr><tr><td></td><td></td><td>Reticul</td><td>ocytes</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Interfering substan</td><td>ices: differ</td><td>rential</td><td></td><td>_</td><td>> 5 NRBCs/100 WBCs, PLT clumps, large PLTs</td><td>> 5 NRBCs/100 WBCs, PLT clumps, large PLTs</td></tr><tr><td>Throughput: max. (</td><td>CBCs per l</td><td>nour/Max</td><td>. CBCs and differentials per hour</td><td>_</td><td>60/60</td><td>60/60</td></tr><tr><td>Minimum specimer</td><td>n volume</td><td>open/Clos</td><td>sed/Sample dead volume closed</td><td>_</td><td>100 μL/100 μL/</td><td>100 µL/100 µL/—</td></tr><tr><td>Instrument prepare</td><td>ollity es microsc</td><td>cope slide</td><td>s automatically/No. of automatic</td><td>_</td><td>no no/—</td><td>yes no/—</td></tr><tr><td>slide makers inst</td><td>talled</td><td>onarately</td><td>or combined unit</td><td></td><td>oold constately</td><td>add congrataly</td></tr><tr><td>• SIIUE IIIdAci Stan</td><td>IEI SUlu Se</td><td>)paratery</td><td>or complitied unit</td><td>_</td><td>Sold Separately</td><td></td></tr><tr><td>Maximum amount</td><td>of archive</td><td>data/Arch ed data ac</td><td>iving is patient specific cessible when system online</td><td><u> </u></td><td>yes/no 100,000 results</td><td>yes/no 100,000 results</td></tr><tr><td>No. specimens for No.</td><td>which nur</td><td>neric resi</td><td>ults saved in memory at once</td><td>X100HT: 45,000; X100: 15,000</td><td>100,000</td><td>100,000</td></tr><tr><td>Instrument perform</td><td>ns delta ch</td><td>io/cylogia necks</td><td>IM results saved in memory at once</td><td>_</td><td>100,000 yes</td><td>100,000 yes</td></tr><tr><td>Parameters for whi</td><td>ich flags n</td><td>nay appea</td><td>ar</td><td>-</td><td>out-of-range flags, measurement condition flags (warnings); flagging on WBC and HGB channels; flagging on BRC/PLT channel/warning flags of differential</td><td>pathological (diagnostic) flags; lab limits (normal ranges); reagents alert (3 measurement pre-alert online reagent re- placement); instrument alerts, internal buffer for reagents</td></tr><tr><td></td><td></td><td></td><td></td><td></td><td>parameters</td><td></td></tr><tr><td>Flagging is operato</td><td>or selectab sults for fo</td><td>)le Ilow-up, (</td><td>confirmatory testing, or rerun</td><td>yes ves</td><td>operator and vendor selectable</td><td> Ves</td></tr><tr><td>Parameters for flag</td><td>gs for hold</td><td>ing samp</td><td>les defined by user or vendor</td><td>user</td><td>user</td><td>user</td></tr><tr><td>Scattergram display Histogram display:</td><td>iy: cell-spe . color with</td><td>ecific colu 1 threshol</td><td>ır ds</td><td><u> </u></td><td>yes ves</td><td>yes ves</td></tr><tr><td>User interface can</td><td>display ch</td><td>noice of s</td><td>pecimen or result information</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>LIS interface formation</td><td>ats suppor</td><td>ted</td><td></td><td>HL7</td><td>proprietary</td><td>proprietary</td></tr><tr><td>Information transfe</td><td>rred via L</td><td>IS interfa</td><td>Ce</td><td>numeric and flag results, instrument to LIS; host query for patient demographics and orders</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient</td></tr><tr><td colspan=2>LOINC codes transmitted with all results/Sent in message to LIS/</td><td>Its/Sent in message to LIS/ soonding LOINC for each test</td><td>yes/yes/—</td><td>demographics and orders yes/yes/yes</td><td>demographics and orders yes/yes/yes</td></tr><tr><td>Interface available Barcode symbologi Accommodates bar</td><td>or planned ies read of ircode plac</td><td>d to autor n specim cement p</td><td>nated specimen-handling system en tube er CLSI standard Auto02-A2</td><td>_ _ _</td><td>no Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5 no</td><td>no Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5 no</td></tr><tr><td>No. of cleaning or r liquid reagents r</td><td>maintenar required</td><td>nce reage</td><td>nts required/No. of routine</td><td>-</td><td>1/3</td><td>1/3</td></tr><tr><td>Time required for d Onboard diagnostic Manufacturer can r</td><td>daily, weel cs for trou perform d</td><td>kly, montl bleshooti iagnostic:</td><td>nly maintenance ng/Limited to software problems s via modem</td><td> yes/no</td><td>daily: automated; weekly: 15–20 minutes yes/no ves</td><td>daily: automated; weekly: 15–20 minutes no/no ves</td></tr><tr><td>Distinguishing feat</td><td>tures (sup)</td><td>olied by c</td><td>ompany)</td><td>full-field imaging provides a digital copy of the patient</td><td>measures 16 parameters including 3-part WBC</td><td>60 samples per hour, volume as low as 110 µL;</td></tr><tr><td></td><td></td><td></td><td></td><td>sample from the monolayer to the feathered edge; built- in remote and IT capabilities utilize the laboratory's own IT infastructure</td><td>differential; efficient manual sampling of open and closed tubes; 60 samples per hour, volume as low as 100 μL</td><td>measures 20 parameters and employs laser-based optical measurement to provide a 5-part WBC differential; aids in interpreting disease state information with 2 scattergrams and 2 histograms per result</td></tr></tbody></table>

[†]does not include slide maker stainers

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

		HEMATOLOGY ANA	LYZERS	OCTOBER 2023 I CAP TODAY 53	
Part 9 of 12		Sight Diagnostics Kevin Lee sales-us@sightdx.com Brooklyn, NY www.sightdx.com/us	Sysmex America Madelaine Dintelman communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us	Sysmex America Madelaine Dintelman communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us	
Name of instrument First year installed in U.S./Outsio No. units installed in U.S./Outs	de U.S./No. of units sold Sept. 2022–Aug. 2023 side U.S./List price†	Sight OLO 2019/2018/ 	pocH-100i 2004/2003/— >2,000/>5,000/\$19,085	XN-330, XN-430, XN-530 2017/2016/— >650/—/\$71,000–\$106,000	
Menu of chartable tests (stan MCHC, PLT, neut %&#, mon Tests submitted for 210(k) cle	dard menu: WBC, RBC, Hb, Hct, MCV, MCH, io, lymph, eos, baso) arance/Tests in development	standard menu plus: RDW, neut %, mono %, lymph %, eos %, baso % —	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, neut %&#, lymph %&#, MXD %&#, RDW-SD, RDW-CV, MPV —</td><td>standard menu plus: IG %&#, MPV, RDW-CV, RDW-SD</td></tr><tr><td>Tests unique to analyzer</td><td></td><td>_</td><td>absolute neutrophil count</td><td> mmature granulocyte on every sample; models available through authorized distributors for POL and clinic market </td></tr><tr><td>Differential method(s) used</td><td></td><td>digital microscopy and computer-vision algorithms</td><td>direct current</td><td>fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light</td></tr><tr><td>Analytical measurement rang</td><td>e: • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes</td><td>0.18–100.13 10³/µL/1.22–7.55 10⁶/µL 4.0–21.75 g/dL/18–1,028.5 10³/µL 15.2–63.7% (Hct) —</td><td>1.0–99.9/0.3–7.0 0.1–25.0/10–999 10–60 (Hct) —</td><td>0.00-440.00/0.00-8.60 0.0-26.0/0-5,000 0.0-75.0% (Hct) —</td></tr><tr><td>Precision: • WBC count/R • Hemoglobin/I • MCV or Hct • Reticulocytes</td><td>BC count Platelet S</td><td>4.1%/2.1% 1.9%/4.8% 2.2% (Hct)</td><td>≤3.5%/≤2.0% ≤1.5%/≤6.0% ≤2.0% (Hct)</td><td><3.0%/<1.5% <1.0%/<4.0% <1.5% (Hct)</td></tr><tr><td>Accuracy of automated differential (per CLSI H20-A</td><td>ential compared with manual 2)</td><td>-</td><td>neut% r=0.98, lymph% r=0.99, MXD% r=0.75, neut# r=1.00, lymph# r=1.00, MXD# r=0.90</td><td>-</td></tr><tr><td>Interfering substances:</td><td>WBC</td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia,</td><td>lyse-resistant RBCs, cold agglutinins, cryoglobulins, PLT aggregation, NRBCs</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis,</td></tr><tr><td></td><td>RBC</td><td>methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia, hynerhiliruhinemia, sulfhemoglobinemia</td><td>cold agglutinins, severe microcytosis, fragmented RBCs</td><td>30.320 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin C. 37.4 mg/dL for bilirubin E 996 mg/dL for bemolysis</td></tr><tr><td></td><td>• MCV or Hct</td><td>methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, mothemoglobinemia, carboxyhemoglobinemia, more</td><td>cold agglutinins, fragmented RBCs, leukocytosis (>100,000/µL)</td><td>30.320 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 20.230 OD for intralipid, 2,890 OD for chyle</td></tr><tr><td>•</td><td>, Platelet</td><td>motenenioglobinemia, carboxynenioglobinemia, more monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, motenenioglobinemia, carboxyhemoglobinemia, more</td><td>PLT aggregation, giant PLTs, microcytic RBCs, fragmented RBCs</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 20.230 0D for interficial 2.880 0D for chula</td></tr><tr><td>•</td><td>• Hemoglobin</td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxybemoglobinemia,</td><td>severe lipemia, abnormal protein, leukocytosis (>100,000/µL)</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis</td></tr><tr><td>•</td><td>Reticulocytes</td><td></td><td>_</td><td>-</td></tr><tr><td>Interfering substances: differe</td><td>ntial</td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more</td><td>_</td><td>_</td></tr><tr><td colspan=2>Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed</td><td>5/5 27 μL// yes no/</td><td>30/30 15 μL/15 μL/15 μL yes no/—</td><td>60/60 25 µL/25 µL/1 mL yes no/—</td></tr><tr><td>Instrument archives patient da</td><td>ata/Archiving is patient specific</td><td>yes/no</td><td>yes/yes</td><td> yes/yes</td></tr><tr><td>Maximum amount of archived No. specimens for which num No. specimens for which histo</td><td>data accessible when system online eric results saved in memory at once n/cvtooram results saved in memory at once</td><td>50,000 results 50,000 —</td><td>100 samples 100 samples 100 samples</td><td>10,000 patient results 10,000 10.000</td></tr><tr><td>Instrument performs delta che Parameters for which flags m</td><td>ecks ay appear</td><td>no IG, blasts, atypical LYM, nRBCs, PLT clumps, giant PLT, RBC agglutination, high reticulocytes, low reticulocytes, WBC agglutination, dual RBC population, more</td><td>yes flagging system suggests sample error for WBC, RBC, PLT parameters</td><td>yes abnormal (user-defined ex: neutrophilia, anisocytosis) and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags for all reportable parameters deemed abnormal ner lab's protocol more</td></tr><tr><td>Flagging is operator selectabl Tags and holds results for follo</td><td>e ow-up, confirmatory testing, or rerun</td><td>no no</td><td>no no</td><td>operator and vendor selectable yes</td></tr><tr><td>Parameters for flags for holdin Scattergram display: cell-spec Histogram display: color with</td><td>ng samples defined by user or vendor cific color thresholds</td><td>vendor no no</td><td>vendor no ves</td><td>yes ves</td></tr><tr><td>User interface can display ch</td><td>oice of specimen or result information</td><td></td><td>yes De page</td><td>yes VN corios ACTM 1381-05/ACTM 1894-97 or XN series</td></tr><tr><td>Information transferred via LIS</td><td>30 S interface</td><td>numeric and flag results, instrument to LIS</td><td>numeric and flag results, histograms and scatterplots, patient demographics, orders, host query for patient demographics and orders</td><td>ASTM 1381-02/ASTM 1894-97 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics</td></tr><tr><td>LOINC codes transmitted with Listing of machine codes ar</td><td>all results/Sent in message to LIS/ nd corresponding LOINC for each test</td><td>no/no/no</td><td>no/no/yes</td><td>and orders yes/yes/no</td></tr><tr><td>Barcode symbologies read on</td><td>specimen tube</td><td>Codabar, Code 39, Code 128, Interleaved 2 of 5, QR</td><td>Code 39, Code 128, ASTM, ITF, NW7, JAN-8, JAN-13</td><td>Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ EAN/UPC</td></tr><tr><td>Accommodates barcode place</td><td>e reagents required/No. of routine</td><td></td><td>no 1/2</td><td>yes</td></tr><tr><td>liquid reagents required Time required for daily, week Onboard diagnostics for troub Manufacturer can perform dia</td><td>ly, monthly maintenance leshooting/Limited to software problems agnostics via modem</td><td>daily: none; weekly: none; monthly: none yes/no yes</td><td>daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes yes/no yes</td><td>daily: 2 minutes; weekly: 15 minutes yes/no yes</td></tr><tr><td>Distinguishing features (suppl</td><td>ied by company)</td><td>2 drops of blood (27 µL) from finger prick or venous sample for patients 3 months or older with any clinical condition; results in less than 10 min. without the need for</td><td>hydrodynamic focusing, automatic floating discriminators, ISBT-compliant, data-masking software for blood donor centers; optional upgrade to pocHi Plus</td><td>6-part WBC differential including immature granulocyte for smaller labs; onboard rules provide efficient repeat testing based on user's criteria; standardization of</td></tr><tr><td>[†]does not include slide make Note: a dash in lieu of an ansı question or question is not ap</td><td>r stainers wer means company did not answer pplicable</td><td>user calibration, external reagents management, or routine maintenance; minimal training required, touchscreen instructions, automatic internal QC and fail-safe system</td><td>or pochi Linc available (data manager and small LIS); ability to directly link to EMR</td><td>reagents and controls with existing Sysmex XN-Series analyzers; BeyondCare Quality Monitor for Hematology, a QC and calibration management program standard on all models</td></tr></tbody></table>		

54 CAP TODAY | OCTOBER 2023 **HEMATOLOGY ANALYZERS** Part 10 of 12 Sysmex America Sysmex America Sysmex America Madelaine Dintelman communications@sysmex.com Jill Crist communications@sysmex.com Jill Crist communications@sysmex.com Lincolnshire. IL Lincolnshire. IL Lincolnshire. IL 800-379-7639 www.sysmex.com/us 800-379-7639 www.svsmex.com/us 800-379-7639 www.sysmex.com/us XN-1000 Series XN-2000 Series Name of instrument XN-350, XN-450, XN-550 First year installed in U.S./Outside U.S./No. of units sold Sept. 2022-Aug. 2023 2012/2011/>175 2017/2015/ 2012/2011/>95 No. units installed in U.S./Outside U.S./List price[†] >1,500/>450/\$202,667 >1,000/>450/\$402,667 >1.450/>3.200/\$75.000-\$110.000 Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, standard menu plus: NRBC %&#, IG %&#, MPV, PLT-F, standard menu plus: NRBC %&#, IG %&#, MPV, PLT-F, standard menu plus: IG %&#. MPV. RDW-CV. RDW-SD MCHC, PLT, neut %&#, mono, lymph, eos, baso) IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&# fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&# Tests submitted for 510(k) clearance/Tests in development Tests for research use only _ IG %&#, PLT-F, IPF, RET-He; body fluids: two-part IG %&#, PLT-F, IPF, RET-He; body fluids: two-part Tests unique to analyzer immature granulocyte on every sample, optional differential MN %&#. PMN %&# differential MN %&#. PMN %&# reticulocyte and body fluid licenses available Differential method(s) used fluorescent flow cytometry with side fluorescent light, fluorescent flow cytometry with side fluorescent light, fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light forward-scattered and side-scattered light forward-scattered and side-scattered light 0 00-440.00/0.00-8.60 0 00-440.00/0.00-8.60 0 00-440.00/0.00-8.60 Analytical measurement range: WBC count/RBC count 0.0-26.0/0-5.000 0.0-26.0/0-5.000 0.0-26.0/0-5.000 Hemoglobin/Platelet • MCV (fL) or Hct (%) 0.0–75.0% (Hct) 0.0-75.0% (Hct) 0.0-75.0% (Hct) Reticulocytes 0.00-30.00 0.00-30.00 WBC count/RBC count <3.0%/<1.5% <3.0%/<1.5% <3.0%/<1.5% Precision: <1.0%/<4.0% Hemoglobin/Platelet <1.0%/<4.0% <1.0%/<4.0% • MCV or Hct <1.5% (Hct) <1.5% (Hct) <1.5% (Hct) Reticulocytes RET %: within ±20% or ±0.30 RET %: ±20% or ±0.3 RET %: ± 20% or ± 0.3 Accuracy of automated differential compared with manual differential (per CLSI H20-A2) no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin Interfering substances: WBC C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 OD for intralipid, 2,880 OD for chyle 30.320 OD for intralipid, 2,880 OD for chyle 30.320 OD for intralipid, 2,880 OD for chyle • RBC no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 OD for intralipid, 2,880 OD for chyle 55.980 OD for intralipid, 2,880 OD for chyle 55.980 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin MCV or Hct no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 OD for intralipid, 2,880 OD for chyle 55.980 OD for intralipid, 2,880 OD for chyle 55.980 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin Platelet C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 OD for intralipid, 2,880 OD for chyle 55,980 OD for intralipid, 2,880 OD for chyle 55.980 OD for intralipid, 2,880 OD for chyle Hemoglobin no significant interference up to: 39.4 mg/dL for bilirubin no significant interference up to: 39.4 mg/dL for bilirubin C, no significant interference up to: 39.4 mg/dL for bilirubin C, C. 37.4 ma/dL for bilirubin F. 199 ma/dL for hemolysis 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis Reticulocytes no significant interference up to: 39.4 mg/dL for bilirubin system may erroneously report a high reticulocyte count system may erroneously report a high reticulocyte with erythrocyte aggregation (cold agglutinin), giant platelets, possibility of PLT clumps, fragmented leukocytes, more count with erythrocyte aggregation (cold agglutinin), giant platelets, possibility of PLT clumps, fragmented C. 37.4 ma/dL for bilirubin F. 1010 ma/dL for hemolysis. 30.320 0D for intralipid, 2,880 0D for chyle leukocytes, more Interfering substances: differential Throughput: max. CBCs per hour/Max. CBCs and differentials per hour 60/60 100/100 200/200 Minimum specimen volume open/Closed/Sample dead volume closed 25 µL/25 µL/1 mL 88 µL/88 µL/1 mL 88 µL/88 µL/1 mL Microsample capability yes yes yes Instrument prepares microscope slides automatically/No. of automatic no/no/no/slide makers installed • Slide maker stainer sold separately or combined unit sold separately (\$180,950) sold separately (\$180,950) Instrument archives patient data/Archiving is patient specific ves/ves ves/ves ves/ves Maximum amount of archived data accessible when system online 100,000 patient results 100.000 samples 100,000 samples No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at once 100 000 100 000 100 000 100,000 100,000 100,000 Instrument performs delta checks yes ves ves Parameters for which flags may appear abnormal (user-defined ex: neutrophilia, anisocytosis) abnormal (user-defined ex: neutrophilia, anisocytosis) abnormal (user-defined ex: neutrophilia, anisocytosis) and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags for all reportable parameters deemed and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags for all reportable parameters deemed and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags all reportable parameters deemed abnormal per lab's protocol, more abnormal per lab's protocol, more abnormal per lab's protocol, more Flagging is operator selectable ves ves Tags and holds results for follow-up, confirmatory testing, or rerun yes yes yes Parameters for flags for holding samples defined by user or vendor user and vendor user and vendor Scattergram display: cell-specific color yes ves ves Histogram display: color with thresholds yes yes yes User interface can display choice of specimen or result information yes ves yes XN series ASTM 1381-95/ASTM 1894-97 or XN series ASTM 1394-91, HL7 ASTM 1394-91, HL7 LIS interface formats supported ASTM 1381-02/ASTM 1894-97 Information transferred via LIS interface numeric and flag results, histograms and scatterplots, numeric and flag results, histograms and scatterplots, numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument to LIS; patient demographics, orders, LIS to instrument to LIS; patient demographics, orders, LIS to instrument-broadcast; host guery for demographics instrument—broadcast; host guery for demographics instrument—broadcast; host guery for demographics and orders and orders and orders LOINC codes transmitted with all results/Sent in message to LIS/ ves/ves/no no/no/ves no/no/ves Listing of machine codes and corresponding LOINC for each test Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ EAN/UPC EAN/UPC EAN/UPC Accommodates barcode placement per CLSI standard Auto02-A2 ves ves ves No. of cleaning or maintenance reagents required/No. of routine 1/4 1/5 cubitainer reagents, 4 fluorescent dye cartridges 1/5 cubitainer reagents, 4 fluorescent dye cartridges liquid reagents required Time required for daily, weekly, monthly maintenance daily: 2 minutes: weekly: 15 minutes daily: <1 minute (operator time) daily: <1 minute (operator time) Onboard diagnostics for troubleshooting/Limited to software problems ves/no yes/no yes/no Manufacturer can perform diagnostics via modem 6-part WBC differential including immature granulocyte reportable parameters include IG %&#. RET-He. Distinguishing features (supplied by company) integrated co-primary hematology solution: 2 analytical for smaller labs; low WBC mode for improved reliability fluorescent PLT, body fluid with 2-part differential; onboard modules connected with a single sampler, provides of analysis; optional reticulocyte and body fluid licenses; preloaded decision rules including automated rerunmaximum productivity and efficiency with workload balancing; reportable parameters include IG %&#, RET-He, fluorescent PLT, body fluid with 2-part differential, onboard rules provide efficient repeat and reflex testing reflex capabilities; optional wagons for complete reagent

[†]does not include slide maker stainers

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

based on user's criteria: standardization of reagents

and controls with existing Sysmex XN-Series analyzers;

BeyondCare Quality Monitor for Hematology, a QC and

calibration management program standard on all models

management: compatible with optional RU-20 reagent

onboard preloaded decision rules including automated

rerun-reflex capabilities; optional wagons for complete

reagent management; compatible with optional RU-20

reagent unit that uses concentrated Cellpack

unit that uses concentrated Cellpack

	HEMATOLOGY ANA	OCTOBER 2023 I CAP TODAY 5	
Part 11 of 12	Sysmex America Jill Crist communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us	Sysmex America Jill Crist communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us	Sysmex America Jill Crist communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us
Name of instrument First year installed in U.S./Outside U.S./No. of units sold Sept. 2022–Aug. 2023 No. units installed in U.S./Outside U.S./List price [†] Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	XN-3100 Series 2017/2017/>60 >500/>25/\$562,667 (includes slide maker stainer) standard menu plus: NRBC %&#, IG %&#, MPV, PLT-F, IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&#</td><td>XN-9100 Series 2017/2017/50 >500/>50/varies based on configuration standard menu plus: NRBC %&#, IG %&#, MPV, PLT-F, IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&#</td><td>XN-V Series* 2017/2017/10 35/28/varies by configuration WBC, RBC, Hb, Hct, MCV, MCH, PLT, neut %&#, mono, lymph, eos, baso, NRBC %&#, MPV, PLT-F, PLT-0, IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids:</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests in development Tests for research use only Tests unique to analyzer</td><td colspan=2></td><td>RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&# — not FDA cleared for human use; for research use only PLT-F, PLT-O, IPF, RET-He; body fluids: 2-part differential</td></tr><tr><td>Differential method(s) used</td><td>differential MN %&#, PMN %&# fluorescent flow cytometry with side fluorescent light.</td><td>differential MN %&#, PMN %&# fluorescent flow cvtometry with side fluorescent light.</td><td>MN %&#, PMN %&# fluorescent flow cytometry with side fluorescent light.</td></tr><tr><td>Analytical measurement range: • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes</td><td>forward-scattered and side-scattered light 0.00–440.00/0.00–8.60 0.0–26.0/0–5,000 0.0–75.0% (Hct) 0.00–30.00</td><td>forward-scattered and side-scattered light 0.00–440.00/0.00–8.60 0.0–26.0/0–5,000 0.0–75.0% (Hct) 0.00–30.00</td><td>forward-scattered and side-scattered light 0.00-440.00/0.00-8.60 0.0-26.0/0-5,000 0.0-75.0% (Hct) —</td></tr><tr><td>Precision: • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes</td><td><3.0%/<1.5% <1.0%/<4.0% <1.5% (Hct) RET %: ± 20% or ± 0.3</td><td><3.0%/<1.5% <1.0%/<4.0% <1.5% (Hct) RET %: = ± 20% or ± 0.3</td><td><3.0%/<1.5% <1.0%/<4.0% <1.5% (Hct)</td></tr><tr><td>Accuracy of automated differential compared with manual</td><td>-</td><td>-</td><td>-</td></tr><tr><td>Interfering substances: • WBC</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 0D for intralipid, 2,880 0D for chyle</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 0D for intralipid, 2,880 0D for chyle</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 30.320 0D for intralipid, 2,880 0D for chyle</td></tr><tr><td>RBC MCV or Hct</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 55.980 0D for intralipid, 2,880 0D for chyle no significant interference up to: 39.4 mg/dL for bilirubin</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 55.980 0D for intralipid, 2,880 0D for chyle no significant interference up to: 39.4 mg/dL for bilirubin</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 55.980 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin</td></tr><tr><td>Platelet</td><td>C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 55.980 0D for intralipid, 2,880 0D for chyle no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis,</td><td>C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 55.980 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis,</td><td>C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, 55.980 OD for intralipid, 2,880 OD for chyle no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis,</td></tr><tr><td>• Hemodlahin</td><td>55.980 OD for intralipid, 2,880 OD for chyle</td><td>55.980 OD for intralipid, 2,880 OD for chyle</td><td>55.980 OD for intralipid, 2,880 OD for chyle</td></tr><tr><td>Reticulocytes</td><td>C, 37.4 mg/dL for bilirubin F, 199 mg/dL for bilirubin system may erroneously report a high reticulocyte count with erythrocyte aggregation (cold agglutinin), giant platelets, possibility of PLT clumps, fragmented leukocytes malaria. Howell- Jolly body</td><td>C, 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis system may erroneously report a high reticulocyte count with erythrocyte aggregation (cold agglutinin), giant platelets, possibility of PLT clumps, fragmented leukocytes malaria. Howell- Jolly body</td><td>C, 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis</td></tr><tr><td>Interfering substances: differential</td><td></td><td></td><td>_</td></tr><tr><td>Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic</td><td>200/200 88 μL/88 μL/1 mL yes yes/1</td><td>$>100,$ varies by configuration/$>100,$ varies by configuration 88 $\mu L/88 \ \mu L/1 \ m L$ yes yes/configurable</td><td>100/100 88 μL/88 μL/1 mL yes yes/—</td></tr><tr><td>slide makers installed • Slide maker stainer sold separately or combined unit</td><td>sold as combined unit</td><td>sold separately (\$180.950) or combined</td><td>_</td></tr><tr><td>Instrument archives patient data/Archiving is patient specific Maximum amount of archived data accessible when system online No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at once</td><td>yes/yes 100,000 samples 100,000 100,000</td><td>yes/yes 100,000 samples 100,000 100,000</td><td>yes/yes 30,000 30,000 30,000</td></tr><tr><td>Parameters for which flags may appear</td><td>abnormal (user-defined ex: neutrophilia, anisocytosis) and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags for all reportable parameters deemed abnormal per lab's protocol, more</td><td>abnormal (user defined ex: neutrophilia, anisocytosis) and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags for all reportable parameters deemed abnormal per lab's protocol, more</td><td></td></tr><tr><td>Flagging is operator selectable Tags and holds results for follow-up, confirmatory testing, or rerun Parameters for flags for holding samples defined by user or vendor Scattergram display: cell-specific color Histogram display: cell-specific color</td><td>yes yes user and vendor yes</td><td>yes yes user and vendor yes</td><td>yes yes yes</td></tr><tr><td>User interface can display choice of specimen or result information</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>LIS interface formats supported</td><td>ASTM 1394-91, HL7</td><td>ASTM 1394-91, HL7</td><td>proprietary, XN series ASTM1381-95/ASTM1894-97 or XN series ASTM1381-02/ASTM1894-97</td></tr><tr><td>Information transferred via LIS interface</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders</td><td>numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders</td></tr><tr><td>Listing of machine codes and corresponding LOINC for each test Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube</td><td>no Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC</td><td>Abbott, QuidelOrtho, Roche, Siemens, Beckman Coulter Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC</td><td>no Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC</td></tr><tr><td>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>No. of cleaning or maintenance reagents required/No. of routine liquid reagents required Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems</td><td> 1/5 cubitainer reagents, 4 fluorescent dye cartridges <3 minutes (operator time), ~15 minutes (analyzer time) ves/no </td><td> 1/5 cubitainer reagents, 4 fluorescent dye cartridges <3 minutes (operator time), ~15 minutes (analyzer time) ves/no </td><td></td></tr><tr><td>Manufacturer can perform diagnostics via modem</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>[†]does not include slide maker stainers Note: a dash in lieu of an answer means company did not answer</td><td>co-primary nematology solution: 2 analytical modules plus fully integrated 5th-gen slidemaker/stainer (SP-50); integration of DI-60 automated cell image system provides preclassification for WBC, RBC, PLT estimates; compatible with optional RU-20 reagent unit that uses concentrated Cellpack; XN-20 configuration has white cell precursor channel (WPC), which differentiates a single for (black (abnormed lumphoritor) into 2 distinct</td><td>standatone scalable, modular automation system or can connect to TLA systems; integration of DI-60 automated cell image system provides preclassification for WBC, RBC, PLT estimates; automated QC (BT-50), tube sorter/ archiver (TS-10, TA-01, TS-01), and A1c testing (Bio-Rad Variant II Turbo Link, Tosoh G8); XN-20 configuration has white cell precursor channel (WPC), which differentiates a single fing (blagt/changemal) into Q differentiates</td><td>customizable, manual gating, low maintenance, remote diagnostics, online QC, fluorescent optical platelets; discrete testing, reagent monitoring, customized chartable report formats; for use in toxicology, research, and veterinary reference labs; available in XN-1000, XN-2000, and XN-3100 configurations</td></tr><tr><td>question or question is not applicable</td><td>single may (blasty abnormal lymphocytes) into 2 distinct flags (blasts and abnormal lymphocytes)</td><td>a single hag (blast/abhormal lymphocytes) into 2 distinct flags (blasts and abnormal lymphocytes)</td><td>איז איז איז איז איז איז איז איז איז איז</td></tr></tbody></table>		

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Part 12 of 12	Sysmex America Madelaine Dintelman communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us	Sysmex America Madelaine Dintelman communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us
Name of instrument First year installed in U.S./Outside U.S./No. of units sold Sept. 2022–Aug. 2023 No. units installed in U.S./Outside U.S./List price [†]	XP-300 2013/2013/— >1,400/>1,000(\$28,405	XW-100 2018/—/— 250/—/\$6,500
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, neut %&#, lymph %&#, MXD %&# (mono, eos, baso), RDW-SD, RDW-CV. MPV</td><td>WBC, RBC, HGB, HCT, MCV, PLT, other WBC %&#, LYM %&#, NEUT %&#</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests in development Tests for research use only Tests unique to analyzer</td><td>absolute neutrophil count</td><td>— — direct current with hydrodynamic focusing for all parameters except hemoglobin, which is measured photometrically</td></tr><tr><td>Differential method(s) used Analytical measurement range: • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes</td><td>direct current 1.0–99.9/0.3–7.0 0.1–25.0/10–999 10–60 (Hct) —</td><td>adaptive cluster analysis 1–63.2/0.3–7.0 0.1–25/10–999 10–60% (Hct) —</td></tr><tr><td>Precision: •WBC count/RBC count •Hemoglobin/Platelet •MCV or Hct •Reticulocytes</td><td><3.5%/<2.0% <1.5%/<6.0% <2.0% (Hct)</td><td><3.5%/<2.0% <1.5%/<6.0% <2.0% (Hct)</td></tr><tr><td>Accuracy of automated differential compared with manual differential (per CLSI H20-A2)</td><td>neut% r=0.98, lymph% r=0.99, MXD% r=0.75, neut# r=1.00, lymph# r=1.00, MXD# r=0.90</td><td>-</td></tr><tr><td>Interfering substances: • WBC • RBC</td><td>cold agglutinins, PLT clumps, cryoprotein, cryoglobulin, fibrin, giant PLTs (>1 M/μL) cold agglutinins, severe microcytosis, fragmented RBCs, lowkeepic (> 100 000/µL) signt PLTs (> 1 M/μL)</td><td>_ _</td></tr><tr><td>MCV or Hct</td><td>cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis (>100,000/μL), severe diabetes, uremia,</td><td>_</td></tr><tr><td>Platelet</td><td>spnerocytosis PLT clumps, pseudothrombocytopenia, giant PLTs, severe microcytosis, fragmented RBCs, fragmented leukocytes, cryoprotein, cryoglobulin</td><td>-</td></tr><tr><td>Hemoglobin</td><td>severe lipemia, abnormal protein, leukocytosis (>100,000/µL)</td><td>-</td></tr><tr><td>Reticulocytes</td><td>—</td><td>—</td></tr><tr><td>Interfering substances: differential</td><td>—</td><td>—</td></tr><tr><td> Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed Slide maker stainer sold separately or combined unit </td><td>60/60 50 μL/—/— yes no/—</td><td>/15 μL/1 mL no no/—</td></tr><tr><td>Instrument archives patient data/Archiving is patient specific Maximum amount of archived data accessible when system online No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at once Instrument performs delta checks Parameters for which flags may appear Flagging is operator selectable Tags and holds results for follow-up, confirmatory testing, or rerun Parameters for flags for holding samples defined by user or vendor Scattergram display: cell-specific color Histogram display: color with thresholds User interface can display choice of specimen or result information</td><td>yes/no 40,000 samples 40,000 no WBC histogram, RBC histogram, PLT histogram, error flags no yes vendor no yes yes yes</td><td>no/no </td></tr><tr><td>LIS interface formats supported Information transferred via LIS interface</td><td>RS-232C numeric and flag results; patient orders, LIS to instrument—broadcast; host query for patient demographics and orders no/no/wes</td><td></td></tr><tr><td>Listing of machine codes and corresponding LOINC for each test Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube</td><td> Codabar, Code 39, Code 128, ITF, NW-7, UPC-A, UPC-E, JAN-8, JAN-13</td><td>no proprietary system (barcodes only)</td></tr><tr><td>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>no</td><td>no</td></tr><tr><td>No. of cleaning or maintenance reagents required/No. of routine liquid reagents required Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems Manufacturer can perform diagnostics via modem</td><td>1/2 daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes yes/no no</td><td>1/2 (1 diluent, 1 lyse) daily: 15 minutes no/no no</td></tr><tr><td>Distinguishing features (supplied by company)</td><td>automatic floating discriminators, optional upgrade to XP-300 Plus or XP-300 Linc available (data manager and small LIS); ability to directly link to EMR</td><td>CLIA-waived CBC; contains several safety measures to protect the integrity of patient results; simple operation</td></tr></tbody></table>	

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[†]does not include slide maker stainers Note: a dash in lieu of an answer means company did not answer question or question is not applicable