Port 1 of 12		Abbett Diagnostics	Abbett Diagnostics	Abbett Diagnostics
Part 1 of 13		Abbott Diagnostics Ihab Zidan ihab.zidan@abbott.com Abbott Park, IL +4916090785918 www.abbottdiagnostics.com	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.abbottdiagnostics.com	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.abbottdiagnostics.com
Name of instrument First year installed in U.S./Outside U.S./ No. units installed in U.S./Outside U.S./		Alinity h-series —/2017/— —/>700/—	CELL-DYN Emerald* 2009/2008/— >1,700/>2,800/\$30,000	CELL-DYN Emerald 22* 2016/2016/— —/—/\$64,000
Menu of chartable tests (standard m MCHC, PLT, neut %&#, mono, lymp Tests submitted for 510(k) clearance/	enu: WBC, RBC, Hb, Hct, MCV, MCH, hh, eos, baso)	——/WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, neut %&#,</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 for research use only</td><td></td><td>mono %&#, lymph %&#, eos %&#, baso %&#, more RDW-SD, microcytic RBC%, macrocytic RBC%, hypochromic RBC%, hyperchromic RBC%, HDW, CHCM, cHGB, MCVr, more</td><td>_</td><td>_</td></tr><tr><td>Tests unique to analyzer</td><td></td><td>_</td><td>_</td><td>_</td></tr><tr><td>Differential method(s) used</td><td></td><td>advanced MAPSS (multi-angle polarized scatter separation) technology using seven light scatter detectors and one fluorescent detector</td><td>electrical impedance counting</td><td>UNI-FLOW Optical Technology</td></tr><tr><td>Analytical measurement range:</td><td>WBC count/RBC count     Hemoglobin/Platelet     MCV (fL) or Hct (%)     Reticulocytes</td><td><math>0.04-447.00\times10^3</math> cells/<math>\mu</math>L/<math>0.01-8.08\times10^6</math> cells/<math>\mu</math>L <math>0.15-24.1</math> g/dL/<math>0.46-5,325\times10^3</math> cells/<math>\mu</math>L 51.4-131.0</math> fL (MCV), <math>9.42-86.0%</math> (Hct) <math>0.05-644\times10^3</math> cells/<math>\mu</math>L</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: • WBC count/RBC count</td><td>nt</td><td>≤3.5 CV% @ >4.0×10<sup>3</sup> cells/μL/≤1.5 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>Hemoglobin/Platelet     MCV or Hct     Patienteetee</td><td></td><td>>4.00×10<sup>6</sup> cells/µL ≤1.3 CV% @ >12.0 g/dL/≤4.5 CV% @ >50.00×10<sup>3</sup> cells/µL ≤1.0 CV% (MCV), ≤2.0 CV% for Hct >45%</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>Reticulocytes  Accuracy of automated differential of differential (per CLSI H20-A2)</td><td>ompared with manual</td><td>≤7.0 CV% @ >200.00×10<sup>3</sup> cells/μL —</td><td>_</td><td>_</td></tr><tr><td>Interfering substances: • WBC</td><td></td><td>cryoglobulin, cryofibrinogen, fragile WBCs, nonviable WBCs, neutrophil aggregates, hemoglobin C crystals, NRBCs, PLT clumps/aggregates</td><td>cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants</td><td>cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants</td></tr><tr><td>• RBC</td><td></td><td>RBC autoagglutinins, cold agglutinins, giant PLTs, RBC fragments</td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/µL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells</td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/µL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells</td></tr><tr><td>• MCV o</td><td>or Hct</td><td>RBC autoagglutinins, cold agglutinins, giant PLTs, PLT clumps/aggregates, hyperglycemia</td><td>cryoglobulin, cryofibrinogen, giant platelets, high white cell count (<math>>50,000~\text{K/µL}</math>), hyperglycemia (<math>>600~\text{mg/dL}</math>), 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>• Platele</td><td>et</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>• Hemo</td><td>globin</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>• Reticu</td><td>llocytes</td><td>RBC autoagglutinins, cold agglutinins, babesiosis, malaria, basophilic stippling, giant PLTs, PLT clumps/aggregates, Howell-Jolly bodies, Heinz bodies, RBC autofluorescence</td><td><u></u></td><td><u></u></td></tr><tr><td>Interfering substances: differential</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: max. CBCs per hour/Max Minimum specimen volume open/Clo</td><td></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 capability Instrument prepares microscope slide</td><td>·</td><td>yes yes/>139</td><td>no no/—</td><td>no/—</td></tr><tr><td>Slide maker stainer sold separately</td><td>or combined unit</td><td>sold as combined unit</td><td>_</td><td>_</td></tr><tr><td>Instrument archives patient data/Arcl Maximum amount of archived data a</td><td></td><td>yes/yes —</td><td>yes/no 300,000 on USB and 1,500 results on internal memory</td><td>yes/no 300,000 on USB and 1,000 records with histograms on internal memory</td></tr><tr><td>No. specimens for which numeric res</td><td>·</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. specimens for which histo/cytogr Instrument performs delta checks</td><td>ř</td><td>most recent 100,000 results yes</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 no</td></tr><tr><td>Parameters for which flags may apper</td><td>ear</td><td>morphological flags including PLT clump, left shift, blast, variant LYM, RBC fragments, more operator and vendor selectable</td><td>dispersional data alerts, suspect measurand flags, and count invalidation flags yes</td><td>dispersional data alerts, suspect parameter flags, and count invalidation flags yes</td></tr><tr><td>Tags and holds results for follow-up, Parameters for flags for holding sam</td><td></td><td>yes user and vendor</td><td>no user</td><td>no user</td></tr><tr><td>Scattergram display: cell-specific col</td><td>or</td><td>yes</td><td>no</td><td>yes</td></tr><tr><td>Histogram display: color with thresho User interface can display choice of</td><td></td><td>yes yes</td><td>no yes</td><td>yes yes</td></tr><tr><td>LIS interface formats supported Information transferred via LIS interfa</td><td>ace</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>LOINC codes transmitted with all resultsting of machine codes and corre</td><td></td><td>no/no/no</td><td>no/no/no</td><td>no/no/no</td></tr><tr><td>Interface available or planned to auto Barcode symbologies read on specim</td><td>mated specimen-handling system nen tube</td><td>Abbott, Inpeco Codabar, Code 39, Code 128, Interleaved 2 of 5</td><td>no 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>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, more</td></tr><tr><td>Accommodates barcode placement p No. of cleaning or maintenance reag</td><td></td><td>yes 1 (Alinity hg module)/3 CBC/diff, 1 retic</td><td>no 1/2</td><td>no 1/2</td></tr><tr><td>liquid reagents required Time required for daily, weekly, mont</td><td></td><td>daily: 0 (automatic) for Alinity hq, hs modules;</td><td>daily: none; weekly: ~15 min.; biannually: ~10 min.</td><td>daily: none; weekly: 15 minutes; quarterly: ~10 minutes</td></tr><tr><td>Onboard diagnostics for troubleshoot Manufacturer can perform diagnostic</td><td></td><td>weekly: 0 (automatic) for Alinity hq, hs modules yes/no no</td><td>no/no no</td><td>no/no no</td></tr><tr><td>Distinguishing features (supplied by o</td><td></td><td>high productivity, scalable systems that use only 3 reagents to provide CBC results with 6-part WBC differential and nRBC; duplicate reagents onboard,</td><td>small: sample size, reagent volumes used, and physical size; reliable: averages one service call per year; easy to use: system has touchscreen software with intuitive</td><td>small physical footprint, only 3 reagents used (2 of 3 reagents stored onboard), and built-in monitor; automated start-up, shut down, and cleaning; 5-part differential using</td></tr><tr><td>†does not include slide maker staine Note: a dash in lieu of an answer me</td><td></td><td>automated daily and weekly maintenance; seamless connectivity to Accelerator a3600 lab automation system</td><td>icons and minimal layers</td><td>UNI-FLOW optical flow cytometry technology with a patented lyse allowing for clear separation of the 5 WBC populations</td></tr><tr><td>question or question is not applicable</td><td></td><td>and AlinIQ middleware</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>		

	Part 2 of 13	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.abbottdiagnostics.com	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.abbottdiagnostics.com	Abbott Diagnostics Christy Thiessen christy.thiessen@abbott.com Abbott Park, IL 800-323-9100 www.abbottdiagnostics.com
	Name of instrument	CELL-DYN Emerald 22 Autoloader*	CELL-DYN Ruby*	CELL-DYN Sapphire*
I	First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022 No. units installed in U.S./Outside U.S./List price <sup>†</sup>	2019/—/— —/—/\$75,000	2006/2006/— >550/>2,700/\$185,000	2005/2005/— >165/>750/\$250,000
	Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	standard menu plus: RDW, MPV, mono %&#, lymph %&#, eos %&#, baso %&#</td><td>standard menu plus: MPV, RDW, retic %&#, neut %&#, mono %&#, lymph %&#, eos %&#, baso %&#</td><td>standard menu plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8, neut %&#, mono %&#, lymph %&#, eos %&#, baso %&#</td></tr><tr><td></td><td>Tests submitted for 510(k) clearance/Tests in development Tests for research use only</td><td>_</td><td>_</td><td>_</td></tr><tr><td></td><td>Tests unique to analyzer</td><td>_</td><td>atypical depolarization flag</td><td>CD61 for PLTs, CD3/4, CD3/8 (immuno T cell)</td></tr><tr><td></td><td>Differential method(s) used</td><td>UNI-FLOW Optical Technology</td><td>MAPSS (multi-angle polarized scatter separation)</td><td>MAPSS (multi-angle polarized scatter separation), three-color fluorescence</td></tr><tr><td></td><td>Analytical measurement range:  • WBC count/RBC count  • Hemoglobin/Platelet  • MCV (fL) or Hct (%)  • Reticulocytes</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><td>0.02–246 <math>\times</math> 10<sup>3</sup>/µL/0.00–7.50 <math>\times</math> 10<sup>6</sup>/µL 0.00–25.0 g/dL/0.00–3,000 <math>\times</math> 10<sup>3</sup>/µL 58–139 (MCV), 8.3–79.8% (Hct)</td><td>0.40-285.5 × 10<sup>3</sup>/µL/0.22-9.06 × 10<sup>6</sup>/µL 0.7-24.8 g/dL/11.0-2,083 × 10<sup>3</sup>/µL 22.1-209.5 fL (MCV) 0.0-1,408 × 10<sup>3</sup>/µL</td></tr><tr><td>ı</td><td>Precision:  • WBC count/RBC count  • Hemoglobin/Platelet</td><td>3.2% CV/2.0% CV 1.2% CV/7.1% CV</td><td>2.4%/1.8% 1.4%/3.8%</td><td><2.7%/≤1.5% ≤1.0%/≤4.0%</td></tr><tr><td>ı</td><td>MCV or Hct</td><td>0.8% CV (MCV)</td><td>0.8% (MCV)</td><td>≤1.0% (MCV)</td></tr><tr><td></td><td>Reticulocytes     Accuracy of automated differential compared with manual</td><td></td><td>0.2–22.9% neut% r=0.983, slope=0.97, y=-1.98; lymph% r=0.921,</td><td>≤15.0% neut% r=0.942, slope=0.947, y=0.446; lymph% r=0.936,</td></tr><tr><td>ı</td><td>differential (per CLSI H20-A2)</td><td>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>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>slope=0.943, y=2.811; mono% r=0.623, slope=1.057, y=0.851; eos% r=0.446, slope=1.024, y=0.288; baso% r=0.232, slope=0.257, y=0.350</td></tr><tr><td>ı</td><td>Interfering substances: • WBC</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>PLT clumps, neutrophil aggregates, HbC crystals, lyse- resistant RBCs, cryoglobulin, cryofibrinogen, fragile WBC, NRBCs</td></tr><tr><td>ı</td><td>• RBC</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>autoagglutination, cold agglutinins, elevated WBC, giant PLTs, hemolysis, sm WBC</td></tr><tr><td>ı</td><td>MCV or Hct</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>autoagglutination, cold agglutinins, elevated WBC, giant PLTs, hemolysis, hyperglycemia, leukocytosis with macrocytic anemia</td></tr><tr><td>ı</td><td>• Platelet</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>auto and cold agglutinins, cryoglobulin, cryofibrinogen, giant PLT, micro RBCs, PLT clumps, RBC fragments, WBC fragments, PLT satellitism</td></tr><tr><td>ı</td><td>• Hemoglobin</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>elevated WBC, increased plasma substances (triglycerides, bilirubin, in vivo hemolysis), lytic-resistant RBCs</td><td>lipids>700 mg/dL, WBCs>250 <math display="inline">\times</math> <math display="inline">10^{9}</math>/L, bilirubin>33 mg/dL, HbC crystals</td></tr><tr><td>ı</td><td>Reticulocytes</td><td>—</td><td>_</td><td>autoagglutinins, babesiosis, basophilic stippling, cold agglutinins, giant PLTs, Howell-Jolly bodies, malaria, PLT clumps, RBC autofluorescence, Heinz bodies</td></tr><tr><td>ı</td><td>Interfering substances: differential</td><td></td><td>fragile WBC, neutrophil aggregates, lytic-resistant RBCs, NRBCs, PLT clumps, cryofibrinogen, cryoglobulin, paraproteins</td><td>see WBC</td></tr><tr><td></td><td>Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead 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>105/105</td></tr><tr><td>ı</td><td>Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed</td><td>no no/—</td><td>no no/—</td><td>yes no/—</td></tr><tr><td>ı</td><td>Slide maker stainer sold separately or combined unit   </td><td></td><td></td><td></td></tr><tr><td>ı</td><td>Instrument archives patient data/Archiving is patient specific  Maximum amount of archived data accessible when system online</td><td>yes/yes 300,000 on USB and 1,000 records with histograms on internal memory</td><td>yes/yes 10,000 results</td><td>yes/yes 10,000 results</td></tr><tr><td>ı</td><td>No. specimens for which numeric results saved 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>10,000 results</td></tr><tr><td>ı</td><td>No. specimens for which histo/cytogram results saved 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>10,000 results</td></tr><tr><td>ı</td><td>Instrument performs delta checks Parameters for which flags may appear</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, ATYPDEP, high-low interp. message, WBC</td><td>yes band, IG, blast, variant lymph, nvWBC, rstRBC, IR, PLT clump, ASYM, FP, CD61 agglutination, clot detected, aspiration, short sample</td></tr><tr><td>ı</td><td>Flagging is operator selectable Tags and holds results for follow-up, confirmatory testing, or rerun</td><td>no yes</td><td>yes yes</td><td>yes yes</td></tr><tr><td>ı</td><td>Parameters for flags for holding samples defined by user or vendor</td><td>vendor</td><td>user</td><td>user</td></tr><tr><td>ı</td><td>Scattergram display: cell-specific color Histogram display: color with thresholds</td><td>yes yes</td><td>yes yes</td><td>yes yes</td></tr><tr><td></td><td>User interface can display choice of specimen or result information</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td></td><td>LIS interface formats supported Information transferred via LIS interface</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— 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 query for patient demographics and orders</td></tr><tr><td></td><td>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>no/no/no</td><td>no/no/no</td></tr><tr><td>ı</td><td>Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube</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</td></tr><tr><td></td><td>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>no</td><td>no</td><td>yes</td></tr><tr><td></td><td>No. of cleaning or maintenance reagents required/No. of routine liquid reagents required</td><td>1/2</td><td>1/3</td><td>0/4</td></tr><tr><td></td><td>Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems Manufacturer can perform diagnostics via modem</td><td>daily: none; weekly: 15 minutes; quarterly: ~10 minutes no/no no</td><td>daily: ~30 seconds; weekly: ~5 min.; monthly: ~10 min. yes/no yes</td><td>daily: ~30 seconds; weekly: ~10 min.; monthly: ~5 min. yes/no yes</td></tr><tr><td></td><td>Distinguishing features (supplied by company)</td><td>small: number of reagents used, footprint, sample size; safe, open tube sampling device; closed tube,</td><td>touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode; rules-</td><td>4 optical and 3 fluorescent detectors provide multiple scatterplot analysis; 2D optical platelets prevent interferences;</td></tr><tr><td></td><td>İdaya nat ingluda alida makar atainara</td><td>continuous autoloading with automated rerun</td><td>based result annotations</td><td>fluorescent analysis of reticulocytes, NRBCs, and 3-color monoclonal analysis; OpenFlow MAb test selections; touch-</td></tr><tr><td></td><td>†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>*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>sensitive screen, interfaces to Accelerator a3600 track system *refer to CELL-DYN Sapphire operator's manual for warnings, limitations, and precautions</td></tr><tr><td></td><td>γασομοτί οι γασομοτί το ποι αμμποανί<del>σ</del></td><td>warningo, iiriilauono, anu picoauliono</td><td>πηταιοπό, από ρισυαυίστο</td><td>πιπταιιοπό, απα ρισυαυίστο</td></tr></tbody></table>		

Part 3 of 13	Advanced Instruments Julie Mackenzie glocyte@aicompanies.com Norwood, MA 781-320-9000 www.aicompanies.com	Beckman Coulter Kanochia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Kanochia Johnson kjohnson05@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. 2021–Aug. 202 No. units installed in U.S./Outside U.S./List price <sup>†</sup>	_	DxH Connected Workcell 2014/2014/— 100/200/\$690,000	DxH SMS II 2018/2018/>15 13/9/\$177,100
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH MCHC, PLT, neut %&#, mono, lymph, eos, baso)	RBC, TNC	standard menu plus: IRF, MPV, MRV, NRBC %&#, RDW-CV, RDW-SD, automated retic #, retic %; body fluids: total nucleated count, RBC count for synovial, serous, CSF fluids, and slidemaking; early sepsis identification (when enabled): MDW</td><td>_</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests in development</td><td>_</td><td>—/immature granulocytes, body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter reticulocytes %&#, more</td><td>_</td></tr><tr><td>Tests for research use only</td><td>_</td><td>retic and extended retic panel: automated retic %&#, MRV, IRF; extended platelet panel: MPV; extended RBC panel: NRBC %&#, RDW-CV, RDW-SD; extended sepsis panel: MDW; more</td><td>_</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; Early Sepsis Indicator; MDW</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></tr><tr><td>Analytical measurement range:   • WBC count/RBC count</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><td>0.050-400.000/0.005-8.500</td><td>_</td></tr><tr><td><ul>     <li>Hemoglobin/Platelet</li>     <li>MCV (fL) or Hct (%)</li> </ul></td><td>_ _</td><td>0.10–25.50/3.0–3,000.0 50.00–150.00 (MCV) for measuring range, 0.00–85.00</td><td>_</td></tr><tr><td>Reticulocytes</td><td>_</td><td>(Hct) for operating range 0.000–30.000</td><td>_</td></tr><tr><td>Precision: • WBC count/RBC count</td><td>TNC: 2.5–18.0% repeatability CV/ 2.7–16.3% repeatability CV</td><td>≤3.0%/≤1.5%</td><td>-</td></tr><tr><td>Hemoglobin/Platelet</td><td>—</td><td>≤1.5%/≤3.5%</td><td>_</td></tr><tr><td>MCV or Hct     Reticulocytes</td><td>Ξ</td><td>≤1.0% (MCV) —</td><td>_</td></tr><tr><td>Accuracy of automated differential compared with manual</td><td>=</td><td>neut= <math>\pm 2.0</math>; lymph, mono= <math>\pm 3.0</math>; eso, baso= <math>\pm 1.0</math> or</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, agglutinated white cells, lyse-</td><td>none</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></tr><tr><td>MCV or Hct</td><td>_</td><td>platelets, autoagglutinins very high WBC count, high concentration of very large</td><td>none</td></tr><tr><td>• Platelet</td><td>_</td><td>platelets, autoagglutinins platelet clumps, white cell fragments, very small red</td><td>none</td></tr><tr><td>Hemoglobin</td><td>_</td><td>cells, red cell fragments, giant platelets, electronic noise severe lipemia, heparin, certain unusual RBC</td><td>none</td></tr><tr><td>Reticulocytes</td><td>_</td><td>abnormalities that resist lysing —</td><td>_</td></tr><tr><td>Interfering substances: differential</td><td>_</td><td>elevated triglycerides, precipitated elevated proteins, hypogranular granulocytes, agranular granulocytes, lyse- resistant red cells, very small or multipopulation lymphocytes</td><td>none</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</td><td>CSFs: ~12/— 60 μL/—/— —</td><td>300/300 165 µL/165 µL/400 µL or 250 µL for MAP tubes yes</td><td>140 slides/— 90 μL/90 μL/250–400 μL yes</td></tr><tr><td>Instrument prepares microscope slides automatically/No. of automatic slide makers installed</td><td>no/—</td><td>yes/—</td><td>yes/—</td></tr><tr><td>Slide maker stainer sold separately or combined unit     Instrument archives patient data/Archiving is patient specific</td><td>— yes/yes</td><td>sold separately (\$165,000) yes/yes</td><td>mo/no</td></tr><tr><td>Maximum amount of archived data accessible when system online  No. specimens for which numeric results saved in memory at once</td><td>— >100,000 results</td><td>up to 100,000 patient results including graphics up to 100,000</td><td>— —</td></tr><tr><td>No. specimens for which histo/cytogram results saved in memory at onc Instrument performs delta checks</td><td></td><td>up to 100,000 yes</td><td> no</td></tr><tr><td>Parameters for which flags may appear Flagging is operator selectable</td><td>control results out of range, expired reagents warning no</td><td>P flag appears on slide with aspiration errors yes</td><td></td></tr><tr><td>Tags and holds results for follow-up, confirmatory testing, or rerun Parameters for flags for holding samples defined by user or vendor</td><td>yes vendor</td><td>yes user and vendor</td><td>no</td></tr><tr><td>Scattergram display: cell-specific color Histogram display: color with thresholds</td><td>no no</td><td>yes yes</td><td>no no</td></tr><tr><td>User interface can display choice of specimen or result information  LIS interface formats supported</td><td>yes RS232, bidirectional</td><td>yes ASTM 1394, ASTM 1238, IEEE MIB, CLSI LISO1-A2</td><td>yes ASTM 1394, ASTM 1238, IEEE MIB, CLSI LIS1-A, CLSI LIS2-A</td></tr><tr><td>Information transferred via LIS interface</td><td>numeric and flag results, instrument to LIS; patient 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 (available with release of Workcell)</td><td>patient demographics, 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</td><td>yes/yes/—</td><td>yes/yes/yes</td><td>no/no/no</td></tr><tr><td>Interface available or planned to automated specimen-handling system Barcode symbologies read on specimen tube</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5, Data Matrix</td><td>Beckman Coulter Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7, ASTM</td><td>NW7</td></tr><tr><td>Accommodates barcode placement per CLSI standard Auto02-A2  No. of cleaning or maintenance reagents required/No. of routine</td><td>yes 0/2 (RBC and TNC reagents)</td><td>yes 1/4</td><td>yes 1 preloaded cube with up to 30 cleaning cycles/3 (can</td></tr><tr><td>liquid reagents required Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems</td><td>minimal annual maintenance required yes/no</td><td>daily: 30 minutes; weekly: none; monthly: none yes/no</td><td>vary): stain, buffer, diluent daily: up to 20 min.; weekly: up to 30 min.; monthly: as needed yes/no</td></tr><tr><td>Manufacturer can perform diagnostics via modem  Distinguishing features (supplied by company)</td><td>no 1 cell/µL limit of detection for RBC and TNC; consistent</td><td>yes Workcell has redundant power supplies, monitors,</td><td>yes hemasphere technology analyzes to overcome variations in</td></tr><tr><td></td><td>turnaround time for standarization and for Lean practices; disposable test cartridges eliminate carryover for infectious samples</td><td>computers, and track systems for independent modular functionality if needed; workload-balancing, proprietary magnetic track system has zero daily, weekly, monthly, yearly maintenance</td><td>blood characteristics to produce an exceptional monolayer smear; flexible rule writing allows for up to 16 slides seamlessly triggered by customizable CBC or specific flag results; blood detector for sample check, flagging directly</td></tr><tr><td><sup>†</sup>does not include slide maker stainers Note: a dash in lieu of an answer means company did not answer</td><td></td><td></td><td>on slide to note aspiration integrity gaps alerting user</td></tr><tr><td>question or question is not applicable</td><td></td><td></td><td></td></tr></tbody></table>	

	Part 4 of 13		Beckman Coulter Kanochia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Kanochia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Kanochia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com
	Name of instrument First year installed in U.S./Outside No. units installed in U.S./Outside	U.S./No. of units sold Sept. 2021–Aug. 2022 de U.S./List price <sup>†</sup>	DxH 520 2019/2018/>300 >20/>700/\$30,000	DxH 560 AL 2020/2021/>150 45/142/\$52,000	DxH 690T 2019/2019/>150 0/10/\$218,000
	Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)		standard menu plus: RDW, RDW-SD, MPV	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></tr><tr><td></td><td>Tests submitted for 510(k) clear Tests for research use only</td><td>rance/Tests in development</td><td>IMM %&#, LHD, MAF, PCT, PDW</td><td>IMM %&#, LHD, MAF, PCT, PDW</td><td>—/immature granulocytes body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter, reticulocytes %&#, low hemoglobin density, more</td></tr><tr><td></td><td>Tests unique to analyzer</td><td></td><td>_</td><td>_</td><td>extended retic panel: MRV; direct count MPV, MCV, MDW, Early Sepsis Indicator: MDW</td></tr><tr><td></td><td>Differential method(s) used</td><td></td><td>optical bench with Coulter digital impedance</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></tr><tr><td>ı</td><td>Analytical measurement range:</td><td>WBC count/RBC count     Hemoglobin/Platelet     MCV (fL) or Hct (%)     Reticulocytes</td><td><math display="block">\begin{array}{c} 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 (MCV)}\\ \end{array}</math></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><math display="block">\begin{array}{l} 0.050-400.00\times10^3~cells/\mu L/0.005-8.500\times10^6~cells/\mu L\\ 0.10-25.50~g/dL/3.0-3,000.0\times10^3~cells/\mu L\\ 50.00-150.00~fL~(MCV, direct measure)\\ 0.000-30.000 \end{array}</math></td></tr><tr><td>ı</td><td>Precision: • WBC count/RBI</td><td>C count</td><td><math display="inline">\leq\!0.20</math> SD when 0.20–3.00 <math display="inline">\times</math> 10 <math display="inline">^3</math> cells/µL, <math display="inline">\leq\!6.00\%</math> CV when >3.00 <math display="inline">\times</math> 10 <math display="inline">^3</math> cells/µL/<math display="inline">\leq\!3.00\%</math> CV @ 3.50–8.00 <math display="inline">\times</math> 10 <math display="inline">^6</math> cells/µL</td><td><math display="inline">\leq\!\!0.20</math> SD when 0.20–3.00×10³ cells/µL, <math display="inline">\leq\!\!6.00\%</math> CV when <math display="inline">>\!\!3.00\!\times\!10^3</math> cells/µL/<math display="inline">\leq\!\!3.00\%</math> CV @ 3.50–8.00×10⁵ cells/µL/<math display="inline">\leq\!\!0.20</math> SD when 0.20–3.00×10³ cells/µL, <math display="inline">\leq\!\!6.00\%</math> CV when</td><td>≤3.0%/≤1.5%</td></tr><tr><td>ı</td><td>• Hemoglobin/Pla</td><td>atelet</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><td>>3.00×10<sup>3</sup> cells/µL/≤3.00% CV @ 3.50–8.00×10<sup>6</sup> 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>≤1.5%/≤3.5% @ 100.0–200.0 × 10<sup>3</sup> cells/µL</td></tr><tr><td>ı</td><td>• MCV or Hct • Reticulocytes</td><td></td><td>≤1.0% (MCV) —</td><td>g/dL/≤10.00% CV @ 100.0−200.0, ≤20.00% CV @ 7.00−100.0 ≤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></tr><tr><td>ı</td><td>Accuracy of automated differer differential (per CLSI H20-A2)</td><td></td><td>NE, LY, M0 <math>\pm 3.00</math>; E0 <math>\pm 1.5</math>; BA <math>\pm 1.0</math> or 10%, whichever is greater</td><td>NE, LY, M0 <math>\pm 3.00</math>; E0 <math>\pm 1.5</math>; BA <math>\pm 1.0</math> or 10%, whichever is greater</td><td>neut <math>\pm 2.0</math>; lymph, mono <math>\pm 3.0</math>; eso and baso <math>\pm 1.0</math> or 10%, whichever is greater</td></tr><tr><td>ı</td><td>Interfering substances: • V</td><td>WBC</td><td>possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells</td><td>possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells</td><td>possibly precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant RBCs, giant PLTs, PLT clumps, unlysed particles >35 fL</td></tr><tr><td>ı</td><td>• F</td><td>RBC</td><td>possibly agglutinated red cells, unlysed RBCs, elevated WBCs, more</td><td>possibly agglutinated red cells, unlysed RBCs, elevated WBCs, more</td><td>possibly very high WBC count, high concentration of very large platelets, autoagglutinins</td></tr><tr><td>ı</td><td></td><td>MCV or Hct</td><td>possibly agglutinated red cells, unlysed RBCs, elevated WBCs, more</td><td>possibly agglutinated red cells, unlysed RBCs, elevated WBCs, more</td><td>possibly very high WBC count, high concentration of very large platelets, autoagglutinins</td></tr><tr><td>ı</td><td></td><td>Platelet</td><td>possibly giant PLTs, platelet clumps, microcytic RBCs, cryoglobulin, white or red cell fragments</td><td>possibly giant PLTs, platelet clumps, microcytic RBCs, 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></tr><tr><td>ı</td><td></td><td>Hemoglobin Reticulocytes</td><td>possibly lipids >62.5 mg/dL (lipemia) —</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 sufficiently numerous within a sample, more</td></tr><tr><td>ı</td><td>Interfering substances: differen</td><td>tial</td><td>possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells</td><td>possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells</td><td>elevated triglycerides, precipitated elevated proteins, hypogranular granulocytes, agranular granulocytes, more</td></tr><tr><td>Г</td><td>Throughput: max. CBCs per hou</td><td>ır/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>55 closed-tube samples, 60 open-tube samples/ 55 closed-tube samples, 60 open-tube samples</td><td>100/100</td></tr><tr><td></td><td>Microsample capability</td><td>en/Closed/Sample dead volume closed e slides automatically/No. of automatic</td><td>16.7 <math>\mu</math>L/16.7 <math>\mu</math>L/1 mL standard tube or 375 <math>\mu</math>L MAP microtainer yes no/—</td><td>16.7 <math>\mu</math>L/16.7 <math>\mu</math>L/1 mL standard tube or 375 <math>\mu</math>L MAP microtainer yes no/—</td><td>165 µL/165 µL/400 µL or 250 µL with MAP tubes yes no/—</td></tr><tr><td></td><td>slide makers installed  • Slide maker stainer sold sepa</td><td>,</td><td>sold separately</td><td>sold separately</td><td>sold separately (\$165,000) or combined</td></tr><tr><td>ь</td><td>Instrument archives patient dat</td><td>•</td><td>yes/yes 30,000 patient results</td><td>yes/yes 30,000 patient results</td><td>yes/yes up to 60,000 patient results</td></tr><tr><td>ı</td><td>No. specimens for which numer</td><td>ric results saved in memory at once cytogram results saved in memory at once</td><td>30,000 patient results 30,000 patient results 30,000 patient results</td><td>30,000 patient results 30,000 patient results 30,000 patient results no</td><td>up to 60,000 patient results up to 60,000 patient results up to 60,000 patient results yes</td></tr><tr><td>ı</td><td>Parameters for which flags may Flagging is operator selectable</td><td>/ appear</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>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></tr><tr><td>ı</td><td>Parameters for flags for holding Scattergram display: cell-specif Histogram display: color with th</td><td>resholds</td><td>yes user yes yes</td><td>yes user yes yes</td><td>yes user yes (3D scatter and surface plots for flow modules) yes</td></tr><tr><td></td><td>LIS interface formats supported Information transferred via LIS i</td><td></td><td>Jese 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><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><td>ASTM 1394-91, ASTM 1238-95, 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 prographics and codes.</td></tr><tr><td>ı</td><td>Listing of machine codes and</td><td>all results/Sent in message to LIS/ corresponding LOINC for each test o automated specimen-handling system</td><td>no/no/no no Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7,</td><td>no/no/no no Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7,</td><td>demographics and orders yes/yes/yes  Beckman Coulter, Roche Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5,</td></tr><tr><td></td><td></td><td>nent per CLSI standard Auto02-A2</td><td>ISBT 128 (donor ID only) yes</td><td>ISBT 128 (donor ID only) yes</td><td>NW7 yes</td></tr><tr><td>ı</td><td>No. of cleaning or maintenance liquid reagents required Time required for daily, weekly, Onboard diagnostics for trouble</td><td>reagents required/No. of routine monthly maintenance shooting/Limited to software problems</td><td>1 preloaded bottle/2 (CBC, diff) daily: 5 min.; weekly: none; monthly: 15 min. yes/no</td><td>1 preloaded bottle/2 (CBC, diff) daily: 5 min.; weekly: none; monthly: 15 min. yes/no</td><td>1 preloaded cube with up to 30 cleaning cycles/3 (CBC, diff, retic [optional]) daily: none (autonomous); weekly: none; monthly: none yes/no</td></tr><tr><td></td><td>Manufacturer can perform diag Distinguishing features (supplie</td><td></td><td>no small aspiration: 16.7 μL for a closed tube, 5-part</td><td>no small aspiration: 16.7 μL for a closed tube, 5-part</td><td>yes  DataFusion uses real-time analytics and bypasses special</td></tr><tr><td></td><td>†does not include slide maker</td><td>stainers er means company did not answer</td><td>differential instrument, ideal for infants and difficult draws; small footprint: requires only 2 reagents for a full CBC/diff; reliable: less than 1 service call per year on average</td><td>differential instrument, ideal for infants and difficult draws; 50 tube load and walkaway capacity; integrated touchscreen and only one external reagent</td><td>modes, avoiding reruns; industry-leading accuracy, precision and low backgrounds with 93% first-pass technology; FDA-cleared Early Sepsis Indicator for early sepsis detection</td></tr></tbody></table>

Part 5 of 13	Beckman Coulter Kanochia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Kanochia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	CellaVision Ken Childs ken.childs@cellavision.com Durham, NC 919-806-4420 www.cellavision.com
Name of instrument First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022 No. units installed in U.S./Outside U.S./List price†	DxH 800 2008/2008/— >2,000/>1,500/\$229,000	DxH 900 2018/2018/>350 80/240/\$259,600	CellaVision DC-1 2021/2019/— —
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, 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, CSF fluids</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><td>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</td></tr><tr><td>Tests submitted for 510(k) clearance/Tests in development</td><td>_</td><td>—/body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter reticulocytes %&#, more</td><td>_</td></tr><tr><td>Tests for research use only  Tests unique to analyzer</td><td>body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter reticulocytes %&#, low hemoglobin density, microcytic anemia factor, mean sphered cell volume, plateletcrit, more —</td><td>body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter reticulocytes %&#, low hemoglobin density, microcytic anemia factor, mean sphered cell volume, plateletcrit, more extended retic panel: MRV; direct count MPV, MCV, MDW,</td><td></td></tr><tr><td>Differential mathed(s) used</td><td>Automobile Intelligent Manufalen, using values</td><td>Early Sepsis Indicator: MDW (when enabled)</td><td>automakad buinktiisid misusaaanu imaga analusia Al</td></tr><tr><td>Differential method(s) used</td><td>Automated Intelligent Morphology using volume, conductivity, 5 angles of light scatter, digital signal processing, advanced algorithm applications, 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><td>automated brightfield microscopy, image analysis, Al</td></tr><tr><td>Analytical measurement range:  • WBC count/RBC count  • Hemoglobin/Platelet  • MCV (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><math display="block">\begin{array}{l} 0.050-400.000\times10^3~cells/\mu L/0.005-8.500\times10^6~cells/\mu L\\ 0.10-25.50~g/dL/3.0-3,000.0\times10^3~cells/\mu L\\ 50.00-150.00~fL \end{array}</math></td><td>_ _ _</td></tr><tr><td>Reticulocytes</td><td>0.000–30.000</td><td>0.000-30.000</td><td>_</td></tr><tr><td>Precision:  • WBC count/RBC count  • Hemoglobin/Platelet  • MCV or Hct</td><td>≤3.0%/≤1.5% ≤1.5%/≤3.5% ≤1.0% (MCV)</td><td>≤3.0%/≤1.5% ≤1.5%/≤3.5% ≤1.0% (MCV)</td><td>=</td></tr><tr><td>Reticulocytes</td><td><u> –                                   </u></td><td></td><td></td></tr><tr><td>Accuracy of automated differential compared with manual differential (per CLSI H20-A2)</td><td>neut= <math>\pm 2.0</math>; lymph, mono= <math>\pm 3.0</math>; eso, baso= <math>\pm 1.0</math> or 10%, whichever is greater</td><td>neut= <math>\pm 2.0</math>; lymph, mono= <math>\pm 3.0</math>; eso, baso= <math>\pm 1.0</math> or 10%, whichever is greater</td><td><math display="block">\label{eq:segnew} \begin{array}{l} \text{seg neu}\%\ y = 0.9904x + 0.37;\  \ \text{ymph}\%\ y = 0.998x + 0.12;\\ \text{mono}\%\ y = 0.9983x + 0.24;\ \text{eos}\%\ y = 0.9912x + 0.03;\\ \text{baso}\%\ y = 0.9427 + 0.08 \end{array}</math></td></tr><tr><td>Interfering substances: • WBC</td><td>precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant RBCs, giant PLTs, PLT clumps, unlysed particles >35 fL in size</td><td>possibly precipitated elevated proteins, cryoglobulin, frag- mented white cells, agglutinated white cells, lyse-resistant RBCs, giant PLTs, PLT clumps, unlysed particles >35 fL</td><td>_</td></tr><tr><td>• RBC</td><td>very high WBC count, high concentration of very large platelets, autoagglutinins</td><td>possibly very high WBC count, high concentration of very large platelets, autoagglutinins</td><td>_</td></tr><tr><td>MCV or Hct</td><td>very high WBC count, high concentration of very large platelets, autoagglutinins</td><td>possibly very high WBC count, high concentration of very large platelets, autoagglutinins</td><td>_</td></tr><tr><td>Platelet</td><td>platelet clumps, white cell fragments, very small red cells, red cell fragments, giant platelets, electronic noise</td><td>possibly platelet clumps, white cell fragments, very small red cells, red cell fragments, giant platelets, electronic noise</td><td>_</td></tr><tr><td>Hemoglobin</td><td>severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing</td><td>possibly severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing</td><td>_</td></tr><tr><td>Reticulocytes</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Interfering substances: differential</td><td>elevated triglycerides, precipitated elevated proteins</td><td>elevated triglycerides, precipitated elevated proteins, hypo- granular granulocytes, agranular granulocytes, lyse-resistant red cells, very small or multipopulation lymphocytes</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</td><td>>100/>90 165 μL/165 μL/250–400 μL</td><td>300 samples/300 samples 165 μL/165 μL/250–400 μL</td><td>—/10 slides —</td></tr><tr><td>Microsample capability Instrument prepares microscope slides automatically/No. of automatic</td><td>yes yes/—</td><td>yes no/—</td><td> no/</td></tr><tr><td>slide makers installed • Slide maker stainer sold separately or combined unit</td><td>- -</td><td></td><td>sold separately</td></tr><tr><td>Instrument archives patient data/Archiving is patient specific</td><td>yes/no</td><td>yes/yes</td><td>yes/no</td></tr><tr><td>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</td><td>up to 100,000 patient results including graphics up to 100,000 patient results including graphics up to 100,000 patient results including graphics</td><td>up to 100,000 patient results including graphics up to 100,000 patient results including graphics up to 100,000 patient results including graphics</td><td>unlimited 1,500 —</td></tr><tr><td>Parameters for which flags may appear Flagging is operator selectable</td><td>flags can be created and customized for all results</td><td>yes —</td><td><u>no</u></td></tr><tr><td>Tags and holds results for follow-up, confirmatory testing, or rerun  Parameters for flags for holding samples defined by user or vendor</td><td>yes yes user and vendor</td><td>yes yes user and vendor</td><td>yes</td></tr><tr><td>Scattergram display: cell-specific color</td><td>yes</td><td>yes (WBC, nRBC, reticulocyte)</td><td>yes, can be imported from the LIS and displayed in the user interface</td></tr><tr><td>Histogram display: color with thresholds User interface can display choice of specimen or result information</td><td>yes yes</td><td>yes (WBC, RBC, PLT) yes</td><td>yes</td></tr><tr><td>LIS interface formats supported Information transferred via LIS interface</td><td>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>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</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></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 system Barcode symbologies read on specimen tube</td><td>yes/yes/yes  Beckman Coulter Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7</td><td>yes/yes/yes  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,</td></tr><tr><td>Accommodates barcode placement per CLSI standard Auto02-A2</td><td>yes</td><td>NW7 yes</td><td>DataMatrix, QR</td></tr><tr><td>No. of cleaning or maintenance reagents required/No. of routine</td><td>1 preloaded cube with up to 30 cleaning cycles/3 (CBC/</td><td>1 preloaded cube with up to 30 cleaning cycles/3 (CBC/</td><td>0/0</td></tr><tr><td>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>diff incl. Coulter Plt, retic, extended retic panel) daily: none (autonomous); weekly: none; monthly: none yes/no yes</td><td>diff incl. Coulter Plt, retic, extended retic panel)  yes/no yes</td><td>daily: none; weekly: 5 min. yes/no no</td></tr><tr><td>Distinguishing features (supplied by company)</td><td>Automated Intelligent Morphology provides 3 independent counts for RBC, WBC, PLT; blast flagging by cell</td><td>DataFusion uses real-time analytics and bypasses special</td><td>network use allows remote review of blood smears and linking of multiple CellaVision analyzers in multiple locations;</td></tr><tr><td>†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>lineage; reliable MPV and reliable hemoglobin with few interferences; 48–72 hour sample stability on CBC parameters</td><td>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><td>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></tr></tbody></table>		

		TIEMATOESST AI		
Part 6 of 13		CellaVision Ken Childs ken.childs@cellavision.com Durham, NC 919-806-4420 www.cellavision.com	Clinical Diagnostic Solutions sales@boule.com Plantation, FL 954-791-1773 www.cdsolinc.com	Diatron MI Frank Matuszak frank.matuszak@diatron.com Medley, FL 833-228-7931 www.diatron.com
Name of instrument First year installed in U.S./Outside U.S./N No. units installed in U.S./Outside U.S		CellaVision DM9600/DM1200 2004/2003/— —/—/~\$135,000-\$175,000	Medonic M-Series 2006/—/— >2,000/>25,000/—	Abacus 3CP 2013/2013/— 56/1,039/\$20,385
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)		neut %&#, mono, lymph, eos, baso, segmented, bands, blast, promyelocytes, myelocytes, metamyelocytes, variant lymphocytes, plasma cells, giant platelets,</td><td>WBC, RBC, HGB, Hct, MCV, MCH, MCHC, PLT, gran %&#, mid, lymph, RDW, MPV</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 for research use only</td><td>Tests in development</td><td>platelet clumps, erythroblasts, more — —</td><td>Ξ</td><td>=</td></tr><tr><td>Tests unique to analyzer</td><td></td><td>analysis of cytocentrifuged samples, body fluids (reported parameters: neutrophils, eosinophils, lymphocytes, macrophages, including monocytes), other (basophils, lymphoma cells, atypical lymphocytes, blast cells, tumor cells)</td><td>micropipette adaptor for capillary sampling</td><td>_</td></tr><tr><td>Differential method(s) used</td><td></td><td>light microscopy, image analysis, artificial neural</td><td>impedance</td><td>volumetric impedance method, light absorbance for</td></tr><tr><td>·</td><td>WD0 1/DD0</td><td>networks</td><td></td><td>HGB measurement</td></tr><tr><td>Analytical measurement range:</td><td>WBC count/RBC count     Hemoglobin/Platelet</td><td>_</td><td>0.5–80.0/0.5–7.00</td><td>0.95–83.45/0.44–7.74 1.4–23.7/11–975</td></tr><tr><td></td><td>MCV (fL) or Hct (%)</td><td>_</td><td>2.0–23.0/30–1,800</td><td>1.4-23.7/11-975 —</td></tr><tr><td></td><td>Reticulocytes</td><td>_</td><td>_</td><td>_</td></tr><tr><td></td><td>•</td><td></td><td></td><td></td></tr><tr><td>Precision: • WBC count/RBC count</td><td>nt</td><td>_</td><td><math>7.0 \times 10^9</math>/L, <math>\le 1.8\%</math> (OT CV)/4.59 <math>\times 10^{12}</math>/L, <math>\le 0.9\%</math> (OT CV)</td><td><2.7%/<1.7%</td></tr><tr><td>Hemoglobin/Platelet     MCV or list</td><td></td><td>_</td><td>14.3 g/dL, <math>\leq</math>0.8% (OT CV)/239 × 10<sup>9</sup>/L, <math>\leq</math>3.0% (OT CV)</td><td><2.0%/<6%</td></tr><tr><td>MCV or Hct     Reticulocytes</td><td></td><td>_</td><td>MCV: 86.8 fL/≤0.5% (OT CV)</td><td><1.7% (MCV and Hct)</td></tr><tr><td>· ·</td><td></td><td></td><td></td><td></td></tr><tr><td>Accuracy of automated differential co differential (per CLSI H20-A2)</td><td>ompared with manual</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><td>_</td></tr><tr><td>Interfering substances: • WBC</td><td></td><td></td><td>NRBCs, unlysed RBCs, hemolysis, leukemias, chemotherapy, cryoglobulins, multiple myeloma, lymphocyte count interference</td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td></tr><tr><td>• RBC</td><td></td><td>_</td><td>leukocytosis with concurrent anemia, agglutinated RBCs, cold agglutinins</td><td>WBC count <math>></math>50.0 <math>\times</math> 10<sup>3</sup>/<math>\mu</math>L</td></tr><tr><td>• MCV or</td><td></td><td><del>-</del></td><td>red blood cell agglutination, WBC, thrombocytosis</td><td>WBC count <math>>50.0 \times 10^3/\mu</math>L</td></tr><tr><td>• Platele</td><td>t</td><td>_</td><td>microcytosis, agglutinated RBCs, giant platelets in excessive numbers, chemotherapy, hemolysis, ACD blood, RBC inclusions, platelet agglutination</td><td>PLT clumps/large PLTs</td></tr><tr><td>• Hemog</td><td>globin</td><td>_</td><td>unlysed RBCs, leukocytosis, lipemia, hyperproteinemia, hyperbilirubinemia, fetal blood</td><td>WBC count <math>></math>50.0 <math>\times</math> 10<math>^3</math>/<math>\mu</math>L, lipids <math>></math>270 mg/dL</td></tr><tr><td>• Reticul</td><td>locytes</td><td>_</td><td>_</td><td>-</td></tr><tr><td>Interfering substances: differential</td><td></td><td>_</td><td>factors that affect WBC plus: large lymphocytes, atypical lymphocytes, blasts, basophils in excessive numbers, metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells in excessive numbers</td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td></tr><tr><td>Throughput: max. CBCs per hour/Max</td><td></td><td>—/35 differentials</td><td>>60/>60</td><td>60/60</td></tr><tr><td>Minimum specimen volume open/Clos Microsample capability</td><td>sea/Sampie dead volume closed</td><td>_</td><td><110 μL/<250 μL/1 mL yes</td><td>100 μL/100 μL/— no</td></tr><tr><td>Instrument prepares microscope slide</td><td>es automatically/No. of automatic</td><td>_</td><td>no/—</td><td>no/—</td></tr><tr><td>slide makers installed • Slide maker stainer sold separately</td><td>or combined unit</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Instrument archives patient data/Arch</td><td></td><td>yes/no</td><td>no/no</td><td>yes/no</td></tr><tr><td>Maximum amount of archived data ad</td><td></td><td>unlimited</td><td>——————————————————————————————————————</td><td>10,000 results</td></tr><tr><td>No. specimens for which numeric resi</td><td></td><td>~4,000</td><td>>1,000 samples</td><td>10,000 results</td></tr><tr><td>No. specimens for which histo/cytogra Instrument performs delta checks</td><td>am results saved in memory at once</td><td>no</td><td>>1,000 samples no</td><td>10,000 results no</td></tr><tr><td>Parameters for which flags may appe</td><td>ar</td><td><u>                                     </u></td><td><u>                                     </u></td><td>range flags, measurement condition flags, parameter</td></tr><tr><td>Flagging is operator coloctoble</td><td></td><td>_</td><td>VAS</td><td>warning, error flags</td></tr><tr><td>Flagging is operator selectable Tags and holds results for follow-up, of</td><td>confirmatory testing, or rerun</td><td>_</td><td>yes no</td><td>no yes</td></tr><tr><td>Parameters for flags for holding samp</td><td>oles defined by user or vendor</td><td>-</td><td>user</td><td>vendor</td></tr><tr><td>Scattergram display: cell-specific cold Histogram display: color with threshol</td><td></td><td>_</td><td>no yes</td><td>no yes</td></tr><tr><td>User interface can display choice of s</td><td></td><td>-</td><td>yes</td><td>no</td></tr><tr><td>LIS interface formats supported</td><td></td><td>ASTM 1394</td><td>through middleware</td><td>HL7, Diatron Serial Communication</td></tr><tr><td>Information transferred via LIS interfa</td><td>ce</td><td>numeric and flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast;</td><td>numeric and flag results, histograms and scatterplots,</td><td>numeric and flag results, histograms and scatterplots,</td></tr><tr><td>I</td><td></td><td>demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>instrument to LIS</td><td>instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</td></tr><tr><td>LOINC codes transmitted with all resu</td><td></td><td>no/no/yes (for peripheral blood)</td><td>no/no/no</td><td>no/no/no</td></tr><tr><td>Listing of machine codes and corres</td><td></td><td>_</td><td>_</td><td>200</td></tr><tr><td>Interface available or planned to autor Barcode symbologies read on specim</td><td></td><td>Codabar, Code 39, Code 128, Interleaved 2 of 5, QR,</td><td>_</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5</td></tr><tr><td></td><td></td><td>DataMatrix</td><td></td><td></td></tr><tr><td>Accommodates barcode placement po</td><td></td><td></td><td>yes</td><td>no</td></tr><tr><td>No. of cleaning or maintenance reage liquid reagents required</td><td>ents required/No. of routine</td><td>none/1</td><td>1/2</td><td>1/3</td></tr><tr><td>Time required for daily, weekly, mont</td><td>hly maintenance</td><td>daily: none; weekly: 5 minutes</td><td>daily: <2 minutes; monthly: 10 minutes; 6 months:</td><td>daily: 10 minutes; weekly: 15 minutes; monthly: 10 minutes</td></tr><tr><td>Onboard diagnostics for troubleshooti Manufacturer can perform diagnostics</td><td></td><td>yes/no no</td><td>75 minutes yes/no no</td><td>no/no no</td></tr><tr><td>Distinguishing features (supplied by c</td><td></td><td>fully automated slide handling and oiling available in</td><td>micropipette adaptor for capillary sampling; 3-part diff</td><td>reliable 3-part diff analyzers with 2 sampling modes</td></tr><tr><td>Distinguishing realtires (supplied by C</td><td>ompany)</td><td>2 models; performs peripheral blood and body fluid</td><td>with auto sampling capability; no weekly maintenance</td><td>(cap-piercing mode for closed-tube sampling and</td></tr><tr><td>I</td><td></td><td>differentials; WBC and other nucleated cells classified into 18</td><td></td><td>another for open tubes); operator safety: self-cleaning</td></tr><tr><td>I</td><td></td><td>categories; RBC morphology characterized for 22 categories; network use allows remote review of blood smears and</td><td></td><td>procedures minimize daily maintenance; user-friendly, easy-to-operate, high-resolution touchscreen; USB and</td></tr><tr><td></td><td></td><td>linking of multiple analyzers in multiple locations</td><td></td><td>barcode option to load QC target values; capable of</td></tr><tr><td>†does not include slide maker staine</td><td></td><td></td><td></td><td>reading QR codes for reference input data; confidence:</td></tr><tr><td>Note: a dash in lieu of an answer mea</td><td></td><td></td><td></td><td>system uses easy-to-understand warning messages and sample flags, employs a comprehensive QC SW package</td></tr><tr><td>question or question is not applicable</td><td>•</td><td></td><td></td><td>puriting a semprenone de our partiage</td></tr></tbody></table>		

Part 7 of 13		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./Outside U.S./No. of units sold Sept. 2021–Aug. 2022 No. units installed in U.S./Outside U.S./List price <sup>†</sup>		Abacus 5 2013/2009/— 35/3,120/\$31,850	Pentra XLR 2016/2015/— —/—/\$77,500	Pentra 60C+ Hematology Analyzer 2000/2000/— >350/>600/\$47,313
Menu of chartable tests (standard me MCHC, PLT, neut %&#, mono, lymph	h, eos, baso)	standard menu plus: RDW-SD, RDW-CV, MPV	standard menu plus: retic %&#, IRF%, CRC%</td><td>standard menu plus: RDW, MPV</td></tr><tr><td>Tests submitted for 510(k) clearance/ Tests for research use only Tests unique to analyzer</td><td>lests in development</td><td></td><td>— PCT, PDW, ATL, LIC automatic dilution for over-range WBC and platelet</td><td>PCT, PDW, ATL, LIC</td></tr><tr><td>Differential method(s) used</td><td></td><td>laser light scatter technology, impedance method, light absorbance</td><td>DHSS technology combining cytochemistry, focused flow impedance, light absorbance</td><td>DHSS technology combining cytochemistry, focused flow impedance, light absorbance principles of measurement</td></tr><tr><td>Analytical measurement range:</td><td>WBC count/RBC count</td><td>0.2-100/0.36-7.19</td><td>0-120 (120-360 with CDR)/0-8</td><td>0-120/0-8</td></tr><tr><td></td><td>Hemoglobin/Platelet</td><td>1.1-22.2/15-2,000</td><td>0-24/0-1,900</math>; 1,900<math>-3,800</math>, Hb >2 g/dL with CDR</td><td>0–24/0–1,900</td></tr><tr><td></td><td>• MCV (fL) or Hct (%)</td><td>_</td><td>0-67% (Hct)</td><td>0-67% (Hct)</td></tr><tr><td></td><td>Reticulocytes</td><td>_</td><td>0–42%</td><td>_</td></tr><tr><td>Precision: • WBC count/RBC coun</td><td>nt</td><td><2.7%/<1.7%</td><td><2%/<2%</td><td><2%/<2%</td></tr><tr><td>Hemoglobin/Platelet</td><td></td><td><2.0%/<6%</td><td><1%/<5%</td><td><1%/<5%</td></tr><tr><td>MCV or Hct</td><td></td><td><1.7% (MCV and Hct)</td><td><2% (Hct)</td><td><2% (Hct)</td></tr><tr><td>Reticulocytes</td><td></td><td>_ ` '</td><td><12%</td><td>_</td></tr><tr><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Accuracy of automated differential co differential (per CLSI H20-A2)</td><td>ompared with manual</td><td>_</td><td>_</td><td>neut% r=0.99, lymph% r=0.98, mono% r=0.96, eos% r=0.89, baso% r=0.54</td></tr><tr><td>Interfering substances: • WBC</td><td></td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td><td>NRBCs, PLT clumps, lyse-resistant RBCs</td><td>NRBCs, PLT clumps, lyse-resistant RBCs</td></tr><tr><td>• RBC</td><td></td><td>WBC count <math>>75.0 \times 10^3/\mu L</math></td><td>cold agglutinins</td><td>cold agglutinins</td></tr><tr><td>• MCV or</td><td>r Hct</td><td>WBC count <math>>75.0 \times 10^3/\mu L</math></td><td>Hct: extreme leukocytosis</td><td>Hct: extreme leukocytosis</td></tr><tr><td>• Platele</td><td>t</td><td>PLT clumps/large PLTs</td><td>microcytes, PLT clumps</td><td>microcytes, PLT clumps</td></tr><tr><td>• Hemog</td><td>alobin</td><td>WBC count >75.0 <math>\times</math> 10<sup>3</sup>/µL, lipids >280 mg/dL</td><td>extreme lipemia, leukocytosis</td><td>extreme lipemia, leukocytosis</td></tr><tr><td>• Reticul</td><td></td><td>_</td><td>same as for RBC</td><td>_</td></tr><tr><td></td><td></td><td>. CAIDDCo/400 WDCo DIT olympag Javas DITa</td><td></td><td>NIDDOs luga vasiatant DDOs autumas hurambilim hiramia</td></tr><tr><td>Interfering substances: differential</td><td></td><td>>5 NRBCs/100 WBCs, PLT clumps, large PLTs</td><td>NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</td><td>NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</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>60/60 110 μL/110 μL/—</td><td>80/80 30 <math display="inline">\mu L</math> for CBC, 53 <math display="inline">\mu L</math> for CBC and differential, 35 <math display="inline">\mu L</math> for reticulocyte/100 <math display="inline">\mu L/</math> —</td><td>60/60 30 μL for CBC, 53 μL for CBC and differential/30 μL for CBC and 53 μL for CBC and differential/—</td></tr><tr><td>Microsample capability Instrument prepares microscope slide</td><td>es automatically/No. of automatic</td><td>no no/—</td><td>yes no/—</td><td>yes no/—</td></tr><tr><td>slide makers installed</td><td></td><td>110/</td><td>110/</td><td>110/</td></tr><tr><td>Slide maker stainer sold separately</td><td>or combined unit</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Instrument archives patient data/Arch Maximum amount of archived data ac</td><td></td><td>yes/no 100,000 results</td><td>yes/yes 10,000 sample results with graphics and numerical data</td><td>yes/yes 10,000 sample results with graphics and numerical data</td></tr><tr><td>No. specimens for which numeric rest</td><td></td><td>100,000 results</td><td>unlimited with backup</td><td>unlimited with backup</td></tr><tr><td>No. specimens for which histo/cytogra</td><td></td><td>100,000 results</td><td>unlimited with backup</td><td>unlimited with backup</td></tr><tr><td>Instrument performs delta checks Parameters for which flags may appea</td><td>ar</td><td>no pathological flags, lab limits (normal ranges), reagents alert, instrument alerts</td><td>yes all CBC and diff parameters have flags</td><td>no all CBC and diff parameters have flags</td></tr><tr><td>Flagging is operator selectable</td><td>confirmatory testing, or rorup</td><td>NO VAS</td><td>NO VAS</td><td>NO VAS</td></tr><tr><td>Tags and holds results for follow-up, or Parameters for flags for holding samp</td><td></td><td>yes vendor</td><td>yes vendor</td><td>yes vendor</td></tr><tr><td>Scattergram display: cell-specific cold</td><td>or</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>Histogram display: color with threshol User interface can display choice of s</td><td></td><td>yes no</td><td>yes no</td><td>yes no</td></tr><tr><td>LIS interface formats supported</td><td></td><td>HL7, Diatron Serial Protocol</td><td>proprietary, ASTM 1394, HL7</td><td>ASTM 1394 and 1238, HL7</td></tr><tr><td>Information transferred via LIS interfac</td><td>ce</td><td>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, patient orders, LIS to instrument—broadcast; host query for patient</td><td>numeric and flag results, histograms and scatter- plots, instrument to LIS; patient demographics, LIS to instrument—broadcast</td></tr><tr><td>LOINC codes transmitted with all resu Listing of machine codes and corres</td><td></td><td>no/no/no</td><td>demographics and orders no/no/no</td><td>no/no/no</td></tr><tr><td>Interface available or planned to autor Barcode symbologies read on specim Accommodates barcode placement po</td><td>mated specimen-handling system en tube</td><td>no Codabar, Code 39, Code 128, Interleaved 2 of 5 yes</td><td>no Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5 yes</td><td>no Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5 yes</td></tr><tr><td>No. of cleaning or maintenance reage</td><td>ents required/No. of routine</td><td>1/3</td><td>2/6</td><td>2/5</td></tr><tr><td>liquid reagents required Time required for daily, weekly, montl</td><td></td><td>daily: 10 minutes; weekly: 15 minutes;</td><td>daily: 10 minutes; weekly: 15 minutes;</td><td>daily: 10 minutes; weekly: 15 minutes;</td></tr><tr><td>Onboard diagnostics for troubleshooti Manufacturer can perform diagnostics</td><td></td><td>monthly: 10 minutes no/no no</td><td>monthly: 15 minutes yes/yes no</td><td>monthly: 15 minutes yes/yes yes, with Data Manager</td></tr><tr><td>Distinguishing features (supplied by c</td><td>company)</td><td>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</td><td>customized dilution ratio for over-range WBC up to <math>360\times10^3</math>/mm³ and platelet up to <math>5,600\times10^3</math>/mm³; auto rerun of patient results based on customized criteria; autovalidation of patient results based on customized criteria; can connect to LiteDM Patient Data Manager, which interfaces with third-party medical devices</td><td>reliable 5-part WBC differential technology; mean time between failures more than 200 days; small footprint; small sample size of 53 µL; can connect to Lite<sup>DM</sup> Patient Data Manager, which interfaces with third-party medical devices</td></tr></tbody></table>	

 $^{\dagger}$ 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

	Part 8 of 13			HORIBA Medical	Mindray	Mindray
				Susan Behnke susan.behnke@horiba.com Irvine, CA 888-903-5001 ext. 4553 www.horiba.com/us/en/medical	Anna Chen a.chen@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com	Anna Chen a.chen@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com
	Name of instrument First year installed in U.S./O No. units installed in U.S./		No. of units sold Sept. 2021–Aug. 2022 S./List price <sup>†</sup>	Pentra XL 80 2004/2003/— >250/>900/\$76,808	BC-5390 2016/2012/— 24/1,612/—	BC-3600 2015/2011/— 78/4,120/—
ĺ	Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)		oh, eos, baso)	standard menu plus: automatic dilution of over-range results (WBC $\times$ 3, RBC/Hgb/PLT $\times$ 2), RDW, MPV	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</td></tr><tr><td></td><td>Tests submitted for 510(k Tests for research use on Tests unique to analyzer</td><td></td><td>/Tests in development</td><td>PCT, PDW, ATL, LIC automatic dilution protocol</td><td>=</td><td>none/none none none</td></tr><tr><td></td><td>Differential method(s) use</td><td>ed</td><td></td><td>DHSS technology combining cytochemistry, focused flow impedance, light absorbance</td><td>flow cytometry, light scatter</td><td>impedance method for WBC, RBC, MCV, RDW, PLT, MPV and WBC 3-part differential determination, colorimetric method for HGB determination</td></tr><tr><td></td><td>Analytical measurement</td><td>range:</td><td>WBC count/RBC count</td><td>0-120/0-8</td><td>0.3-200/0.2-8.0</td><td>0.3–99.9/0.20–7.99</td></tr><tr><td></td><td></td><td></td><td>Hemoglobin/Platelet</td><td>0-24/0-1,900 (>2 g/dL Hb)</td><td>0.5–25/5–2,000</td><td>1.0–24.9/10–999</td></tr><tr><td>ı</td><td></td><td></td><td>MCV (fL) or Hct (%)     Reticulocytes</td><td>0-2,800 (<2 g/dL Hb), 0-67% (Hct)</td><td>2–75% (Hct) —</td><td>_</td></tr><tr><td>ı</td><td>Precision: • WBC cou</td><td>int/RBC cou</td><td>nt</td><td><2%/<2%</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></tr><tr><td></td><td>, and the second se</td><td>bin/Platelet</td><td></td><td><1%/<5%</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></tr><tr><td>ı</td><td>MCV or F     Reticulor</td><td></td><td></td><td><2% (Hct) —</td><td><1.5% (MCV) —</td><td>≤2.0 CV% (MCV), ≤2.5% CV% (Hct) —</td></tr><tr><td>ı</td><td>Accuracy of automated d differential (per CLSI H</td><td></td><td>ompared with manual</td><td>neut% r=0.99, lymph% r=0.98, mono% r=0.96, eos% r=0.89, baso% r=0.54</td><td>neu%: <math>\pm 5.00</math> or <math>\pm 10.0\%</math>; lym%: <math>\pm 4.00</math> or <math>\pm 10.0\%</math>; mon%: <math>\pm 3.00</math> or <math>\pm 10.0\%</math>; eos%: <math>\pm 2.00</math> or <math>\pm 10.0\%</math>; bas%: <math>\pm 1.00</math> or <math>\pm 10.0\%</math></td><td>_</td></tr><tr><td></td><td>Interfering substances:</td><td>• WBC</td><td></td><td>NRBCs, PLT clumps, lyse-resistant RBCs</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></tr><tr><td>ı</td><td></td><td>• RBC</td><td></td><td>cold agglutinins</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></tr><tr><td>ı</td><td></td><td>• MCV o</td><td>or Hct</td><td>Hct: extreme leukocytosis</td><td>RBC fragments, very high WBC count, high concentration of very large platelets, microclots, RBC rouleaux or agglutinates (autoagglutination)</td><td>very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments</td></tr><tr><td></td><td></td><td>• Platele</td><td>et</td><td>microcytes, PLT clumps</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></tr><tr><td>ı</td><td></td><td>Hemo</td><td>globin</td><td>extreme lipemia, leukocytosis</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></tr><tr><td></td><td></td><td>Reticu</td><td>ılocytes</td><td>_</td><td>_</td><td>—</td></tr><tr><td></td><td>Interfering substances: di</td><td>fferential</td><td></td><td>NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia</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></tr><tr><td></td><td>Minimum specimen volur</td><td></td><td>x. CBCs and differentials per hour osed/Sample dead volume closed</td><td>80/80 30 µL for CBC/53 µL for CBC and differential/0.5 mL</td><td>60/60 100 μL/33 μL, predilute 20 μL/1 mL</td><td>60/60 100 μL/21 μL, predilute 20 μL/1 mL</td></tr><tr><td></td><td>slide makers installed</td><td></td><td>es automatically/No. of automatic</td><td>yes no/—</td><td>yes no/—</td><td>yes no/—</td></tr><tr><td>ı</td><td><ul>     <li>Slide maker stainer sole</li>     <li>Instrument archives patie</li> </ul></td><td></td><td></td><td>yes/yes</td><td></td><td></td></tr><tr><td></td><td>Maximum amount of arch</td><td>nived data a</td><td>ccessible when system online</td><td>10,000 sample results with graphics and numerical data</td><td></td><td>40,000 results</td></tr><tr><td></td><td>No. specimens for which</td><td>histo/cytogi</td><td>sults saved in memory at once ram results saved in memory at once</td><td>unlimited with backup unlimited with backup</td><td>100,000 100,000</td><td>40,000 40,000</td></tr><tr><td>ı</td><td>Instrument performs delta Parameters for which flag</td><td></td><td>ear</td><td>yes all CBC and diff parameters have flags</td><td>yes immature gran? Abn/atypical lym? RBC agglutination? iron deficiency? PLT clump? NRBC? blasts? RBC lyse resist?</td><td><u>no</u></td></tr><tr><td>ı</td><td>Flagging is operator selec</td><td>ctable</td><td></td><td>no</td><td>leukocytosis, leukopenia, anemia, anisocytosis, more operator and vendor selectable</td><td>no</td></tr><tr><td></td><td></td><td></td><td>confirmatory testing, or rerun ples defined by user or vendor</td><td>yes vendor</td><td>yes —</td><td>no </td></tr><tr><td></td><td>Scattergram display: cell- Histogram display: color v</td><td>-specific col</td><td>lor</td><td>yes yes</td><td>yes yes</td><td>no yes</td></tr><tr><td></td><td></td><td></td><td>specimen or result information</td><td>no</td><td>yes</td><td>no</td></tr><tr><td></td><td>LIS interface formats sup</td><td></td><td></td><td>proprietary, ASTM 1394 and 1238, HL7</td><td>HL7</td><td>HL7</td></tr><tr><td></td><td>Information transferred vi</td><td>ia lis iliteria</td><td>ace</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, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast</td></tr><tr><td></td><td></td><td></td><td>ults/Sent in message to LIS/ esponding LOINC for each test</td><td>no/no/no</td><td>yes/yes/yes</td><td>yes/yes/no</td></tr><tr><td></td><td></td><td>nned to auto</td><td>omated specimen-handling system</td><td>no Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5</td><td>none Codabar, Code 39, Code 93, Code 128, Interleaved 2 of 5, UPC/EAN</td><td>Codabar, Code 39, Code 128</td></tr><tr><td></td><td></td><td></td><td>per CLSI standard Auto02-A2</td><td>yes o/F</td><td>_</td><td>_</td></tr><tr><td></td><td>No. of cleaning or mainte liquid reagents require</td><td></td><td>ents required/No. of routine</td><td>2/5</td><td>1/4</td><td>1/4</td></tr><tr><td></td><td>Time required for daily, w Onboard diagnostics for t Manufacturer can perforn</td><td>roubleshoot</td><td>ting/Limited to software problems</td><td>daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes no/yes no</td><td>daily: <10 minutes yes/no yes</td><td>daily: <10 minutes yes/no no</td></tr><tr><td></td><td>Distinguishing features (s</td><td></td><td></td><td>compact 5-part differential instrument with autoloader</td><td>60 QC files; maximum 40 samples autoloader capacity,</td><td>10.4-inch all-in-one Glance color touchscreen, touch-</td></tr><tr><td></td><td>†does not include slide n</td><td>naker staine</td><td>ers</td><td>and autodilution capability, auto rerun feature, autovalidation; can connect to Lite<sup>DM</sup> Patient Data</td><td>sample adaptors for pediatric and predilution samples; operation software with built-in data-management</td><td>button maintenance procedures, and low sample requirement; 40,000 patient results storage, close-tube</td></tr><tr><td></td><td>Note: a dash in lieu of an</td><td>answer me</td><td>ans company did not answer</td><td>Manager, which interfaces with third-party medical devices</td><td>functions, 3 modes of operation: autoloader and opened and closed tube; customizable patient reports; only 1 maintenance reagent</td><td>sampling, open-tube sampling for pediatric samples; 3 types of sample adaptors, barcoded reagent, and 5 minutes daily start-up and maintenance</td></tr><tr><td></td><td>question or question is no</td><td>л аррпсавы</td><td><del>5</del></td><td></td><td>тапонано годуби</td><td>mmatoo dany olare-up and maintenance</td></tr></tbody></table>	

Part 9 of 13		PixCell Medical Ryan Venturi info@pixcell-medical.com Longmont, CO 888-615-4122 www.pixcell-medical.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 instrument First year installed in U.S./Outside U.S No. units installed in U.S./Outside U	5./No. of units sold Sept. 2021–Aug. 2022 I.S./List price <sup>†</sup>	HemoScreen 2018/2016/—	Advia 360 Hematology System 2015/2015/— —	Advia 560/560AL Hematology System 2015/2015/— —
	menu: WBC, RBC, Hb, Hct, MCV, MCH, nph, eos, baso)	standard menu plus: MPV, RDW	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
Tests for research use only Tests unique to analyzer	e/ rests in development			
Differential method(s) used		digital microscopy and computer-vision algorithms	volumetric impedance change for WBC, RBC, PLT; lytic	volumetric impedance change for WBC, RBC, PLT; light
, ,			reagents with impedance method for 3 subpopulations; spectrophotometry for HGB	scattering baso measurement; light scattering 4-diff measurement LYM, MON, NEU, EOS; spectrophotometry for HGB
Analytical measurement range:	WBC count/RBC count	$0.5-80.0 \times 10^3 / \mu L / 1.0 - 8.8 \times 10^6 / \mu L$	0.0-85.0/0.00-8.00	0.20-100.0/0.36-7.19
	Hemoglobin/Platelet	3.0–25.0 g/dL/20–800 × 10 <sup>3</sup> /μL	0.0–25.0/0–1,000	1.10–22.2/15.0–1,000
	MCV (fL) or Hct (%)	9.0–78.0% (Hct)	50–120 (MCV)	50–120 (MCV)
	Reticulocytes	<del>-</del>	_	_
Precision: • WBC count/RBC co	punt	4.0%/1.5%	<4.0%/<2.5%	<3.4%/<2.0%
Hemoglobin/Platele	et	1.6%/3.5%	<2.4%/<7.0%	<2.4%/<7.0%
MCV or Hct		1.6% (Hct)	<2.0% (MCV)	<2.0% (MCV)
Reticulocytes		_	_	-
Accuracy of automated differential differential (per CLSI H20-A2)	compared with manual	_	-	-
Interfering substances: • WBC	:	no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides	>5 NRBCs/100 WBCs, PLT clumps, large PLTs	>5 NRBCs/100 WBCs, PLT clumps, large PLTs
• RBC		no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides	WBC count $>75.0 \times 103/\mu L$	WBC count >75.0 × 103/μL
• MCV	or Hct	no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides	WBC count >75.0 × 103/μL	WBC count >75.0 × 103/μL
• Plate	elet	no significant interference up to 30 mg/dL bilirubin, 729 mg/dL triglycerides	PLT clumps, large PLTs	PLT clumps, large PLTs
• Hem	oglobin	no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides	WBC count >75.0 $\times$ 103/ $\mu$ L, lipids >280 mg/dL	WBC count >75.0 × 103/μL, lipids >280 mg/dL
• Retio	culocytes	<del>-</del>	_	-
Interfering substances: differential		_	> 5 NRBCs/100 WBCs, PLT clumps, large PLTs	> 5 NRBCs/100 WBCs, PLT clumps, large PLTs
Throughput: max. CBCs per hour/M		20/10	60/60	60/60
Minimum specimen volume open/C Microsample capability	losed/Sample dead volume closed	40 μL/40 μL/— yes	100 μL/100 μL/— no	100 μL/100 μL/— yes
Instrument prepares microscope sli	ides automatically/No. of automatic	no/—	no/—	no/—
<ul><li>slide makers installed</li><li>Slide maker stainer sold separate</li></ul>	ely or combined unit	_	sold separately	sold separately
Instrument archives patient data/Ar		yes/no	yes/no	yes/no
Maximum amount of archived data No. specimens for which numeric r		1,000 1,000	100,000 results 100,000	100,000 results 100,000
No. specimens for which histo/cyto	gram results saved in memory at once	_	100,000	100,000
Instrument performs delta checks Parameters for which flags may ap	pear	no all CBC and differential parameters have flags;	yes out-of-range flags, measurement condition flags	yes pathological (diagnostic) flags; lab limits (normal
, , ,		pathological flags, range flags, measurement condition flags, parameter warning, error flags	(warnings); flagging on WBC and HGB channels; flagging on RBC/PLT channel/warning flags of differential parameters	ranges); reagents alert (3 measurement pre-alert online reagent replacement); instrument alerts, internal buffer for reagents
Flagging is operator selectable		no	operator and vendor selectable	—
Tags and holds results for follow-up Parameters for flags for holding sai		NO vonder	yes	yes
Scattergram display: cell-specific c	olor	vendor no	user yes	user yes
Histogram display: color with thresl User interface can display choice of	10lds of specimen or result information	NO VAS	yes	yes
LIS interface formats supported	opolitici of tesult illiotiliation	yes HL7, POCT-1A	yes proprietary	yes proprietary
Information transferred via LIS inter	rface	numeric and flag results, instrument to LIS	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders
LOINC codes transmitted with all re		yes/yes/yes	yes/yes	yes/yes
Listing of machine codes and cor	responding LOINC for each test tomated specimen-handling system	no	no	no
Barcode symbologies read on spec	imen tube	Codabar, Code 39, Code 128, Interleaved 2 of 5	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5
Accommodates barcode placement	·	0.00	no 1/2	no 1/2
No. of cleaning or maintenance rea liquid reagents required		0/0	1/3	1/3
Time required for daily, weekly, mo Onboard diagnostics for troublesho Manufacturer can perform diagnosi	oting/Limited to software problems	none yes/no yes	daily: automated; weekly: 15–20 minutes yes/no yes	daily: automated; weekly: 15–20 minutes no/no yes
Distinguishing features (supplied by		cartridge-based 5-part differential CBC analyzer FDA-	measures 16 parameters including 3-part WBC	60 samples per hour, volume as low as 110 μL;
Z.cg.louid of (ouppriod b)	, <del></del>	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	differential; efficient manual sampling of open and closed tubes; 60 samples per hour, volume as low as 100 µL	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
I				

†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

Part 10 of 13		Siemens Healthineers	Sight Diagnostics	Sysmex America
		Sheryl Kirk sheryl.kirk@siemens-healthineers.com Tarrytown, NY 469-390-7319 siemens-healthineers.com/hematology	Kevin Lee sales-us@sightdx.com Brooklyn, NY www.sightdx.com/us	Madelaine Dintelman communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us
Name of instrument First year installed in U.S./Ou No. units installed in U.S./O	utside U.S./No. of units sold Sept. 2021–Aug. 2022 Outside U.S./List price <sup>†</sup>	Advia 2120i Hematology System 2008/2008/— 698/3,900/\$245,700	Sight OLO 2019/2018/—	pocH-100i 2004/2003/— >2,000/>5,000/\$19,085
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)		standard menu plus: CHCM, RDW, HDW, CH, CHDW, LUC, NRBC, MPV, PDW, PCT, RETIC, MCVr, MCVg, CHCMg, CHCMr, CHg, CHr, large PLT, 9 RBC morphology	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></tr><tr><td>Tests submitted for 510(k) Tests for research use only</td><td>clearance/Tests in development</td><td>classification flags, more —/sepsis, MPC, MPM  IRF, CSF eos, MPC, MPM, PCDW, PCT, PDW, PLT N, PLT X, PLT Y, PMDW, P count—2D, R count—2D, RBC Count—2D, PLT N, PLT Y, PMDW, PCC, PMD PMC Count—2D, PMDW, PMD</td><td></td><td>=</td></tr><tr><td>Tests unique to analyzer</td><td></td><td>RtcPlts%, RtcPltsCount, RtcPltsThreshold, RtcPlt VI, more chartable RBC morphology, large PLT enumeration, CHr, CHCM, HDW, CHDW, CHCMr, CHg, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono</td><td>_</td><td>absolute neutrophil count</td></tr><tr><td>Differential method(s) used</td><td>1</td><td>peroxidase WBC: peroxidase cytochem. staining with light scatter and absorption; baso: cytochem. stripping with 2-angle laser light scatter</td><td>digital microscopy and computer-vision algorithms</td><td>direct current</td></tr><tr><td>Analytical measurement ra</td><td>• WBC count/RBC count     • Hemoglobin/Platelet     • MCV (fL) or Hct (%)     • Reticulocytes</td><td>0.02-400 × 103/μL/0-7.0 × 106/μL 0-22.5 g/dL/5-3,500 × 103/μL 30-180 (MCV) 0.2-24.5%</td><td>0.18–100.13 10<sup>3</sup>/µL/1.22–7.55 10<sup>6</sup>/µL 4.0–21.75 g/dL/18–1,028.5 10<sup>3</sup>/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></tr><tr><td>Precision:  WBC coun  Hemoglob  MCV or Ho  Reticulocy</td><td>ct</td><td>2.7%/1.2% 0.93%/2.93% 0.78% (MCV)</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></tr><tr><td>· ·</td><td>fferential compared with manual</td><td>neut% r=0.997, y=1.02x-0.6; lymph% r=0.997, y=1.00x+0.8; mono% r=0.943, y=0.85x-0.3; eos% r=0.979, y=0.87x+0.2; baso% r=0.772, y=0.67x+0.0; luc% r=0.994, y=0.92+0.6</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></tr><tr><td>Interfering substances:</td><td>• WBC</td><td>incomplete RBC lysis (peroxidase only)</td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more</td><td>lyse-resistant RBCs, cold agglutinins, cryoglobulins, PLT aggregation, NRBCs</td></tr><tr><td></td><td>• RBC</td><td>cold agglutinins, extreme sickle cell</td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more</td><td>cold agglutinins, severe microcytosis, fragmented RBCs</td></tr><tr><td></td><td>MCV or Hct     Platelet</td><td></td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia,</td><td>cold agglutinins, fragmented RBCs, leukocytosis (>100,000/µL)  PLT aggregation, giant PLTs, microcytic RBCs,</td></tr><tr><td></td><td>Hemoglobin</td><td>extreme lipemia, high WBC, extremely high bilirubin;</td><td>hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia,</td><td>fragmented RBCs severe lipemia, abnormal protein, leukocytosis</td></tr><tr><td></td><td>Reticulocytes</td><td>colorimetric: none with cellular Hgb</td><td>hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more</td><td>(>100,000/µL)</td></tr><tr><td>Interfering substances: diff</td><td>ferential</td><td>incomplete RBC lysis, complete myeloperoxidase deficiency</td><td>monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more</td><td>_</td></tr><tr><td>Minimum specimen volum Microsample capability Instrument prepares micro slide makers installed</td><td>er hour/Max. CBCs and differentials per hour ne open/Closed/Sample dead volume closed oscope slides automatically/No. of automatic</td><td>120/120 175 μL/175 μL/<300 μL (tube-size dependent) yes yes/—</td><td>5/5 ~30 µL/—/— yes no/—</td><td>30/30 15 μL/15 μL/15 μL yes no/—</td></tr><tr><td></td><td>separately or combined unit at data/Archiving is patient specific</td><td>sold separately (\$107,016) yes/yes</td><td>— yes/no</td><td>— yes/yes</td></tr><tr><td>Maximum amount of archive No. specimens for which n</td><td>ved data accessible when system online numeric results saved in memory at once histo/cytogram results saved in memory at once</td><td>10,000 patient results, incl. graphics 10,000 patient results, incl. graphics 10,000 patient results, incl. graphics</td><td>50,000 results 50,000</td><td>100 samples 100 samples 100 samples</td></tr><tr><td>Parameters for which flags</td><td>s may appear</td><td>yes left shift, atypical lymphocytes, blasts, immature grans, myeloperoxidase deficiency, aniso, micro, macro, Hgb variation, hypo, hyper, NRBC, RBC fragments, RBC, more</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></tr><tr><td></td><td>follow-up, confirmatory testing, or rerun</td><td>operator and vendor selectable yes</td><td>no no</td><td>no no</td></tr><tr><td>Parameters for flags for ho Scattergram display: cell-s</td><td>olding samples defined by user or vendor specific color</td><td>user yes</td><td>vendor no</td><td>vendor no</td></tr><tr><td>Histogram display: color w</td><td>ith thresholds</td><td>yes</td><td>no</td><td>yes</td></tr><tr><td>LIS interface formats supp</td><td>choice of specimen or result information orted</td><td>yes proprietary, ASTM 1394-91, ASTM 1238-95, ASTM 1381,</td><td>yes HL7</td><td>yes RS-232C</td></tr><tr><td>Information transferred via</td><td></td><td>Atellica Data Manager provides HL7 compatibility 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, instrument to LIS</td><td>numeric and flag results, histograms and scatterplots, patient demographics, orders, host query for patient demographics and orders</td></tr><tr><td>Listing of machine codes</td><td>with all results/Sent in message to LIS/ s and corresponding LOINC for each test ned to automated specimen-handling system</td><td>no/no/yes Siemens, Sysmex</td><td>no/no/no</td><td>no/no/yes</td></tr><tr><td>Barcode symbologies read</td><td>on specimen tube</td><td>Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5, JAN (8 and 13), ISBT 128</td><td>none Codabar, Code 39, Code 128, Interleaved 2 of 5, QR</td><td>Code 39, Code 128, ASTM, ITF, NW7, JAN-8, JAN-13</td></tr><tr><td></td><td>lacement per CLSI standard Auto02-A2 nance reagents required/No. of routine</td><td>yes 5/3</td><td>0/0</td><td>no 1/2</td></tr><tr><td>liquid reagents required</td><td></td><td>daily: none; weekly: automated wash sequence; monthly:</td><td>daily: none; weekly: none; monthly: none</td><td>daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes</td></tr><tr><td></td><td>oubleshooting/Limited to software problems</td><td>15 minutes yes/no</td><td>yes/no</td><td>yes/no</td></tr><tr><td>Manufacturer can perform</td><td>diagnostics via modem</td><td>yes</td><td>yes</td><td>yes</td></tr><tr><td>Distinguishing features (su</td><td> 3,</td><td>dual WBC counts with a linearity of up to 400,000; CSF true zero; laser technology provides direct cellular Hgb for RBCs and reticulocytes; 2D optical PLT analysis</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></tr><tr><td>†does not include slide ma Note: a dash in lieu of an a question or question is not</td><td>answer means company did not answer</td><td>eliminates interference from RBC fragments and inclusion of large PLTs</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></tr><tr><td></td><td></td><td></td><td>,</td><td></td></tr></tbody></table>

Part 11 of 13	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	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. 2021–Aug. 2022 No. units installed in U.S./Outside U.S./List price†	XN-330, XN-430, XN-530 2017/2016/— >650/—/\$71,000–\$106,000	XN-350, XN-450, XN-550 2017/2015/— >1,450/>3,200/\$75,000—\$110,000	XN-1000 Series 2012/2011/>175 >1,500/>450/\$202,667
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	standard menu plus: IG %&#, MPV, RDW-CV, RDW-SD</td><td>standard menu plus: IG %&#, MPV, RDW-CV, RDW-SD</td><td>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></tr><tr><td>Tests submitted for 510(k) clearance/Tests in development Tests for research use only Tests unique to analyzer</td><td>— — immature granulocyte on every sample; models available through authorized distributors for POL and clinic market</td><td>mature granulocyte on every sample, optional reticulocyte and body fluid licenses available</td><td>IG %&#, PLT-F, IPF, RET-He; body fluids: two-part differential MN %&#, PMN %&#</td></tr><tr><td>Differential method(s) used</td><td>fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light</td><td>fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light</td><td>fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light</td></tr><tr><td>Analytical measurement range:  • WBC count/RBC count  • Hemoglobin/Platelet  • MCV (fL) or Hct (%)  • Reticulocytes</td><td>0.00–440.00/0.00–8.60 0.0–26.0/0–5,000 0.0–75.0% (Hct)</td><td>0.00-440.00/0.00-8.60 0.0-26.0/0-5,000 0.0-75.0% (Hct)</td><td>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></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)</td><td><3.0%/<1.5% <1.0%/<4.0% <1.5% (Hct) RET %: within ±20% or ±0.30</td><td><3.0%/<1.5% <1.0%/<4.0% <1.5% (Hct) RET %: ±20% or ±0.3</td></tr><tr><td>Accuracy of automated differential compared with manual differential (per CLSI H20-A2)</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 OD for intralipid, 2,880 OD 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 OD for intralipid, 2,880 OD for chyle</td></tr><tr><td>• RBC</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 OD for intralipid, 2,880 OD 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 OD for intralipid, 2,880 OD 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, 55.980 OD for intralipid, 2,880 OD for chyle</td></tr><tr><td>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, 30.320 OD for intralipid, 2,880 OD 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 OD for intralipid, 2,880 OD 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, 55.980 OD for intralipid, 2,880 OD for chyle</td></tr><tr><td>Platelet</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 OD for intralipid, 2,880 OD 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 OD for intralipid, 2,880 OD 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, 55.980 OD for intralipid, 2,880 OD for chyle</td></tr><tr><td>Hemoglobin</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><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><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>Reticulocytes</td><td>_</td><td>no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 1010 mg/dL for hemolysis, 30.320 OD for intralipid, 2,880 OD for chyle</td><td>system may erroneously report a high reticulocyte count with erythrocyte aggregation (cold agglutinin), giant platelets, possibility of PLT clumps, fragmented leukocytes, more</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 slide makers installed</td><td>60/60 25 μL/25 μL/1 mL yes no/—</td><td>60/60 25 μL/25 μL/1 mL yes no/—</td><td>100/100 88 μL/88 μL/1 mL yes no/—</td></tr><tr><td>Slide maker stainer sold separately or combined unit     Instrument archives patient data/Archiving is patient specific</td><td>yes/yes</td><td></td><td>sold separately (\$180,950) yes/yes</td></tr><tr><td>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</td><td>10,000 patient results 10,000 10,000 yes</td><td>100,000 patient results 100,000 100,000 yes</td><td>100,000 samples 100,000 100,000 yes</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>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></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</td><td>operator and vendor selectable yes —</td><td>yes —</td><td>yes yes user and vendor</td></tr><tr><td>Scattergram display: cell-specific color Histogram display: color with thresholds User interface can display choice of specimen or result information</td><td>yes yes yes</td><td>yes yes yes</td><td>yes yes yes</td></tr><tr><td>LIS interface formats supported</td><td>XN series ASTM 1381-95/ASTM 1894-97 or XN series</td><td>XN series ASTM 1381-95/ASTM 1894-97 or XN series</td><td>ASTM 1394-91, HL7</td></tr><tr><td>Information transferred via LIS interface</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 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 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>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>yes/yes/no no</td><td>yes/yes/no no</td><td>no/no/yes no</td></tr><tr><td>Barcode symbologies read on specimen tube  Accommodates barcode placement per CLSI standard Auto02-A2</td><td>Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ EAN/UPC yes</td><td>Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ EAN/UPC yes</td><td>Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/ EAN/UPC yes</td></tr><tr><td>No. of cleaning or maintenance reagents required/No. of routine</td><td>1/4</td><td>1/4</td><td>1/5 cubitainer reagents, 4 fluorescent dye cartridges</td></tr><tr><td>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>daily: 2 minutes; weekly: 15 minutes yes/no yes</td><td>daily: 2 minutes; weekly: 15 minutes yes/no yes</td><td>daily: <1 minute (operator time) yes/no yes</td></tr><tr><td>Distinguishing features (supplied by company)</td><td>6-part WBC differential including immature granulocyte</td><td>6-part WBC differential including immature granulocyte</td><td>reportable parameters include IG %&#, RET-He,</td></tr><tr><td><math>^{\dagger}</math>does not include slide maker stainers</td><td>for smaller labs; onboard rules provide efficient repeat testing 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</td><td>for smaller labs; low WBC mode for improved reliability of analysis; optional reticulocyte and body fluid licenses available; onboard rules provide efficient repeat and reflex testing 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</td><td>fluorescent PLT, body fluid with 2-part differential; onboard preloaded decision rules including automated rerunreflex capabilities; optional wagons for complete reagent management; compatible with optional RU-20 reagent unit that allows for use of concentrated Cellpack</td></tr><tr><td>Note: a dash in lieu of an answer means company did not answer</td><td></td><td>all models</td><td></td></tr></tbody></table>		

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

Part 12 of 13 **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.svsmex.com/us 800-379-7639 www.svsmex.com/us 800-379-7639 www.svsmex.com/us XN-2000 Series XN-3100 Series XN-9100 Series First year installed in U.S./Outside U.S./No. of units sold Sept. 2021-Aug. 2022 2012/2011/>95 2017/2017/>60 2017/2017/50 No. units installed in U.S./Outside U.S./List price<sup>†</sup> >1.000/>450/\$402.667 >500/>25/\$562.667 (includes slide maker stainer) >500/>50/varies based on configuration 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, IPF, standard menu plus: NRBC %&#, IG %&#, MPV, PLT-F, MCHC, PLT, neut %&#, mono, lymph, eos, baso) IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&# 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 IG %&#, PLT-F, IPF, RET-He; body fluids: 2-part Tests unique to analyzer differential MN %&#, PMN %&# differential MN %&#, PMN %&# differential MN %&#. PMN %&# 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 Analytical measurement range: WBC count/RBC count 0.00-440.00/0.00-8.60 0.00-440.00/0.00-8.60 0.00-440.00/0.00-8.60 • Hemoglobin/Platelet 0.0-26.0/0-5,000 0.0-26.0/0-5,000 0.0-26.0/0-5,000 MCV (fL) or Hct (%) 0.0-75.0% (Hct) 0.0-75.0% (Hct) 0.0-75.0% (Hct) 0.00-30.00 0.00-30.00 0.00 - 30.00 Reticulocytes WBC count/RBC count <3.0%/<1.5% <3.0%/<1.5% <3.0%/<1.5% Precision: Hemoglobin/Platelet <1.0%/<4.0% <1.0%/<4.0% <1.0%/<4.0% MCV or Hct <1.5% (Hct) <1.5% (Hct) <1.5% (Hct) Reticulocytes RET %:  $\pm$  20% or  $\pm$  0.3 RET %:  $\pm$  20% or  $\pm$  0.3 RET %: =  $\pm$  20% or  $\pm$  0.3 Accuracy of automated differential compared with manual differential (per CLSI H20-A2) Interfering substances: WBC 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 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. 55.980 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 C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, no significant interference up to: 39.4 mg/dL for bilirubin C, 37.4 mg/dL for bilirubin F, 996 mg/dL for hemolysis, no significant interference up to: 39.4 mg/dL for bilirubin · MCV or Hct C. 37.4 mg/dL for bilirubin F. 996 mg/dL for hemolysis. 55.980 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, 55.980 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 C, no significant interference up to: 39.4 mg/dL for bilirubin Hemoglobin 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis C, 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis C, 37.4 mg/dL for bilirubin F, 199 mg/dL for hemolysis system may erroneously report a high reticulocyte system may erroneously report a high reticulocyte system may erroneously report a high reticulocyte Reticulocytes count with erythrocyte aggregation (cold agglutinin), count with erythrocyte aggregation (cold agglutinin), count with erythrocyte aggregation (cold agglutinin), giant platelets, possibility of PLT clumps, fragmented giant platelets, possibility of PLT clumps, fragmented giant platelets, possibility of PLT clumps, fragmented leukocytes, more leukocytes, malaria, Howell-Jolly body leukocytes, malaria, Howell-Jolly body Interfering substances: differential Throughput: max. CBCs per hour/Max. CBCs and differentials per hour 200/200 varies by configuration/varies by configuration >100, varies by configuration/>100, varies by configuration Minimum specimen volume open/Closed/Sample dead volume closed  $88 \mu L/88 \mu L/1 mL$ 88 μL/88 μL/1 mL 88 μL/88 μL/1 mL Microsample capability yes yes yes/1 yes/configurable Instrument prepares microscope slides automatically/No. of automatic no/ slide makers installed sold separately (\$180,950) sold as combined unit sold separately (\$180,950) or combined • Slide maker stainer sold separately or combined unit Instrument archives patient data/Archiving is patient specific Maximum amount of archived data accessible when system online 100,000 samples 100,000 samples 100,000 samples No. specimens for which numeric results saved in memory at once 100.000 100.000 100.000 No. specimens for which histo/cytogram results saved in memory at once 100,000 100,000 100.000 Instrument performs delta checks yes 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 yes yes 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 user and vendor Scattergram display: cell-specific color Histogram display: color with thresholds yes yes yes yes yes ves User interface can display choice of specimen or result information yes yes yes LIS interface formats supported ASTM 1394-91, HL7 ASTM 1394-91, HL7 ASTM 1394-91, HL7 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 query for demographics instrument—broadcast: host query for demographics instrument—broadcast; host query for demographics and orders LOINC codes transmitted with all results/Sent in message to LIS/ no/no/ves 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 Abbott, Ortho Clinical, Roche, Siemens, Beckman Coulter Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/  $\,$ Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC Barcode symbologies read on specimen tube Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC EAN/UPC Accommodates barcode placement per CLSI standard Auto02-A2 ves No. of cleaning or maintenance reagents required/No. of routine 1/5 cubitainer reagents, 4 fluorescent dye cartridges 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 Onboard diagnostics for troubleshooting/Limited to software problems daily: <1 minute (operator time) <3 minutes (operator time), ~15 minutes (analyzer time) <3 minutes (operator time), ~15 minutes (analyzer time) ves/no yes/no ves/no Manufacturer can perform diagnostics via modem yes yes yes Distinguishing features (supplied by company) fully integrated co-primary hematology solution co-primary hematology solution: 2 analytical modules scalable, modular system that can be configured as consisting of 2 analytical modules connected with a plus a fully integrated 5th-generation slidemaker/stainer an island of automation or connected to TLA systems; single sampler, providing maximum productivity and efficiency with workload balancing; reportable parameters (SP-50); integration of the DI-60 automated cell image integration of the DI-60 automated cell image system system, providing preclassification for WBC, RBC, and providing preclassification for WBC, RBC, and PLT include IG %&#, RET-He, fluorescent PLT, body fluid with PLT estimates; compatible with optional RU-20 reagent estimates; tube sorter/archiver (TS-10) and A1c testing 2-part differential, onboard preloaded decision rules unit that allows for use of concentrated Cellpack; (Bio-Rad Variant II Turbo Link) provide complete testing including automated rerun-reflex capabilities; optional optional configuration (XN-20) possesses the white cell efficiencies; optional configuration (XN-20) possesses the

wagons for complete reagent management; compatible

with optional RU-20 reagent unit that allows for use of

concentrated Cellpack

precursor channel (WPC), which differentiates a single

flag (blast/abnormal lymphocytes) into 2 distinct flags

(blasts and abnormal lymphocytes)

white cell precursor channel (WPC), which differentiates

a single flag (blast/abnormal lymphocytes) into 2 distinct

flags (blasts and abnormal lymphocytes)

†does not include slide maker stainers

question or question is not applicable

Note: a dash in lieu of an answer means company did not answer

Part 13 of 13		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	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. 2021–Aug. 2022 No. units installed in U.S./Outside U.S./List price <sup>†</sup>		XN-V Series* 2017/2017/10 35/28/varies by configuration	XP-300 2013/2013/— >1,400/>1,000/\$28,405	XW-100 2018/—/— 250/—/\$6,500
Menu of chartable tests (stan MCHC, PLT, neut %&#, mor	dard menu: WBC, RBC, Hb, Hct, MCV, MCH, o, lymph, eos, baso)	WBC, RBC, Hb, Hct, MCV, MCH, PLT, neut %&#, mono, lymph, eos, baso, NRBC %&#, MPV, PLT-F, PLT-O, IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&#</td><td>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) cle Tests for research use only Tests unique to analyzer</td><td>arance/Tests in development</td><td>not FDA cleared for human use; for research use only PLT-F, PLT-0, IPF, RET-He; body fluids: 2-part differential MN %&#, PMN %&#</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</td><td></td><td>fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light</td><td>direct current</td><td>adaptive cluster analysis</td></tr><tr><td>Analytical measurement rang</td><td><ul><li>Hemoglobin/Platelet</li><li>MCV (fL) or Hct (%)</li></ul></td><td>0.00-440.00/0.00-8.60 0.0-26.0/0-5,000 0.0-75.0% (Hct)</td><td>1.0–99.9/0.3–7.0 0.1–25.0/10–999 10–60 (Hct)</td><td>1–63.2/0.3–7.0 0.1–25/10–999 10–60% (Hct)</td></tr><tr><td></td><td>Reticulocytes</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Precision: • WBC count/R</td><td></td><td><3.0%/<1.5%</td><td><3.5%/<2.0%</td><td><3.5%/<2.0%</td></tr><tr><td>Hemoglobin/     MCV or Hot</td><td>rialeiet</td><td><1.0%/<4.0%</td><td><1.5%/<6.0%</td><td><1.5%/<6.0%</td></tr><tr><td>MCV or Hct     Reticulocytes</td><td></td><td><1.5% (Hct)</td><td><2.0% (Hct)</td><td><2.0% (Hct)</td></tr><tr><td></td><td></td><td></td><td>nout9/, r=0.09 (smah9/, r=0.00 MVD9/ = 0.75 ==0.51</td><td></td></tr><tr><td>Accuracy of automated differ differential (per CLSI H20-A</td><td>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>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 OD for intralipid, 2,880 OD for chyle</td><td>cold agglutinins, PLT clumps, cryoprotein, cryoglobulin, fibrin, giant PLTs (>1 M/µL)</td><td>_</td></tr><tr><td>•</td><td>• RBC</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</td><td>cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis (>100,000/μL), giant PLTs (>1 M/μL)</td><td>_</td></tr><tr><td>·</td><td>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 OD for intralipid, 2,880 OD for chyle</td><td>cold agglutinins, severe microcytosis, fragmented RBCs, leukocytosis (>100,000/µL), severe diabetes, uremia, spherocytosis</td><td>_</td></tr><tr><td>·</td><td>Platelet</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</td><td>PLT clumps, pseudothrombocytopenia, giant PLTs, severe microcytosis, fragmented RBCs, fragmented leukocytes, cryoprotein, cryoglobulin</td><td>_</td></tr><tr><td></td><td>Hemoglobin</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><td>severe lipemia, abnormal protein, leukocytosis (>100,000/µL)</td><td>_</td></tr><tr><td>•</td><td>Reticulocytes</td><td>_</td><td>_</td><td>_</td></tr><tr><td>Interfering substances: differen</td><td>ential</td><td>_</td><td>_</td><td>-</td></tr><tr><td>Minimum specimen volume of Microsample capability</td><td>our/Max. CBCs and differentials per hour pen/Closed/Sample dead volume closed ope slides automatically/No. of automatic parately or combined unit</td><td>100/100 88 µL/88 µL/1 mL yes yes/—</td><td>60/60 50 µL/—/— yes no/—</td><td></td></tr><tr><td>Instrument archives patient d</td><td>ata/Archiving is patient specific</td><td>yes/yes</td><td>yes/no</td><td>no/no</td></tr><tr><td>No. specimens for which num No. specimens for which hist Instrument performs delta ch Parameters for which flags m</td><td>ay appear</td><td>30,000 30,000 30,000 yes</td><td>40,000 samples 40,000 40,000 no WBC histogram, RBC histogram, PLT histogram, error flags</td><td>TOO TOO WBC, RBC, PLT, HGB, HCT</td></tr><tr><td>Flagging is operator selectable Tags and holds results for foll</td><td>e ow-up, confirmatory testing, or rerun</td><td>— yes</td><td>no yes</td><td>no no</td></tr><tr><td>Parameters for flags for holdi</td><td>ng samples defined by user or vendor</td><td><del>_</del></td><td>vendor</td><td>vendor</td></tr><tr><td>Scattergram display: cell-spe Histogram display: color with User interface can display ch</td><td></td><td>yes yes yes</td><td>no yes yes</td><td>no no no</td></tr><tr><td>LIS interface formats support</td><td>ed</td><td>proprietary, XN series ASTM1381-95/ASTM1894-97 or</td><td>RS-232C</td><td>_</td></tr><tr><td>Information transferred via Ll</td><td>S interface</td><td>XN series ASTM1381-02/ASTM1894-97 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; patient orders, LIS to instrument—broadcast; host query for patient demographics and orders</td><td>_</td></tr><tr><td>Listing of machine codes ar</td><td>all results/Sent in message to LIS/ nd corresponding LOINC for each test to automated specimen-handling system</td><td>yes/yes/no</td><td>no/no/yes</td><td>no/no/no</td></tr><tr><td>Barcode symbologies read on</td><td></td><td>no Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC</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></td><td>ement per CLSI standard Auto02-A2</td><td>yes</td><td>no</td><td>no</td></tr><tr><td>No. of cleaning or maintenan liquid reagents required</td><td>ce reagents required/No. of routine</td><td><del>-</del></td><td>1/2</td><td>1/2 (1 diluent, 1 lyse)</td></tr><tr><td>Time required for daily, week</td><td>leshooting/Limited to software problems</td><td>daily: <1 minute (operator time) yes/no yes</td><td>daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes yes/no no</td><td>daily: 15 minutes no/no no</td></tr><tr><td>Distinguishing features (supp</td><td></td><td>customizable, manual gating, low maintenance, remote</td><td>automatic floating discriminators, optional upgrade to</td><td>CLIA-waived CBC; contains several safety measures to</td></tr><tr><td>†does not include slide make</td><td></td><td>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><td>XP-300 Plus or XP-300 Linc available (data manager and small LIS); ability to directly link to EMR</td><td>protect the integrity of patient results; simple operation</td></tr><tr><td>Note: a dash in lieu of an ans</td><td>wer means company did not answer</td><td>XN-2000, and XN-3100 configurations  *XN-V Series is not FDA cleared for human use; for research</td><td></td><td></td></tr><tr><td>question or question is not ap</td><td></td><td>use only.</td><td></td><td></td></tr></tbody></table>		