

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	Alinity h-series	CELL-DYN Emerald*	CELL-DYN Emerald 22*	
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	—/2017/—	2009/2008/—	2016/2016/—	
No. units installed in U.S./Outside U.S./List price†	—/—/700/—	>1,700/>2,800/\$30,000	—/—/\$64,000	
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	—	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, lymph %&#, gran %&#, mid %&#, RDW, MPV	standard menu plus: RDW, MPV, mono %&#, lymph %&#, eos %&#, baso %&#	
Tests submitted for 510(k) clearance/Tests in development	—/WBC, RBC, Hb, Hct, MCV, MCH, MCHC, Plt, neut %&#, mono %&#, lymph %&#, eos %&#, baso %&#, more	—	—	
Tests for research use only	RDW-SD, microcytic RBC%, macrocytic RBC%, hypochromic RBC%, hyperchromic RBC%, HDW, CHCM, cHGB, MCVr, more	—	—	
Tests unique to analyzer	—	—	—	
Differential method(s) used	advanced MAPSS (multi-angle polarized scatter separation) technology using seven light scatter detectors and one fluorescent detector	electrical impedance counting	UNI-FLOW Optical Technology	
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	0.4–447.00 × 10 ³ cells/μL/0.01–8.08 × 10 ⁶ cells/μL 0.15–24.1 g/dL/0.46–5.325 × 10 ³ cells/μL 51.4–131.0 fL (MCV), 9.42–86.0% (Hct) 0.05–644 × 10 ³ cells/μL	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)	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)
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	≤3.5 CV% @ >4.0 × 10 ³ cells/μL/≤1.5 CV% @ >4.00 × 10 ⁶ cells/μL ≤1.3 CV% @ >12.0 g/dL/≤4.5 CV% @ >50.00 × 10 ³ cells/μL ≤1.0 CV% (MCV), ≤2.0 CV% for Hct >45% ≤7.0 CV% @ >200.00 × 10 ³ cells/μL	3.5% (95% confidence limit)/2.0% (95% confid. limit) 2.1% (95% confidence limit)/6.1% (95% confid. limit) 0.8% MCV (95% confid. limit), 1.7% Hct (95% confid. limit)	3.2% CV/2.0% CV 1.2% CV/7.1% CV 0.8% CV (MCV)
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	—	—	—	
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	cryoglobulin, cryofibrinogen, fragile WBCs, nonviable WBCs, neutrophil aggregates, hemoglobin C crystals, NRBCs, PLT clumps/aggregates RBC autoagglutinins, cold agglutinins, giant PLTs, RBC fragments RBC autoagglutinins, cold agglutinins, giant PLTs, PLT clumps/aggregates, hyperglycemia RBC autoagglutinins, cold agglutinins, cryoglobulin, cryofibrinogen, giant PLTs, PLT clumps/aggregates, PLT satellitism, RBC fragments, more hemoglobin C crystals RBC autoagglutinins, cold agglutinins, babesiosis, malaria, basophilic stippling, giant PLTs, PLT clumps/aggregates, Howell-Jolly bodies, Heinz bodies, RBC autofluorescence	cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), hyperglycemia (>600 mg/dL), autoagglutination, clotting, in vitro hemolysis, more cryoglobulin, cryofibrinogen, in vivo and in vitro hemolysis, microcytic red cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin, platelet, more carboxyhemoglobin (>10%), cryoglobulin, cryofibrinogen, in vivo hemolysis, heparin, high white cell count (>50,000 K/μL), hyperbilirubinemia, lipemia, monoclonal proteins, clotting	cryoglobulin, cryofibrinogen, heparin, monoclonal proteins, nucleated red cells, platelet clumping, unlysed red cells, clotting, smudge cells, uremia plus immunosuppressants cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), autoagglutination, clotting, in vitro hemolysis, microcytic red cells cryoglobulin, cryofibrinogen, giant platelets, high white cell count (>50,000 K/μL), hyperglycemia (>600 mg/dL), autoagglutination, clotting, in vitro hemolysis, more cryoglobulin, cryofibrinogen, in vivo and in vitro hemolysis, microcytic red cells, red cell inclusions, white cell fragments, clotting, giant platelets, heparin, platelet, more carboxyhemoglobin (>10%), cryoglobulin, cryofibrinogen, in vivo hemolysis, heparin, high white cell count (>50,000 K/μL), hyperbilirubinemia, lipemia, monoclonal proteins, clotting
Interfering substances: differential	cryoglobulin, cryofibrinogen, fragile WBCs, nonviable WBCs, neutrophil aggregates, hemoglobin C crystals, NRBCs, PLT clumps/aggregates	platelet aggregates, NRBCs, giant platelets, cryoglobulin, incomplete lysis of RBCs, small lymphocytes, fibrin clots, shift in WBC cell distrib. due to EDTA anticoagulant equilibration	platelet aggregates, erythroblasts, small lymphocytes, immature cells, resistant RBCs, giant or hypersegmented neutrophils, bands	
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	—/119	57/57	45/45	
Minimum specimen volume open/Closed/Sample dead volume closed	≤100 μL/≤100 μL/dependent on tube	9.8 μL/—/—	17 μL/—/—	
Microsample capability	yes	no	no	
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	yes/>139	no/—	no/—	
• Slide maker stainer sold separately or combined unit	sold as combined unit	—	—	
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/no	yes/no	
Maximum amount of archived data accessible when system online	—	300,000 on USB and 1,500 results on internal memory	300,000 on USB and 1,000 records with histograms on internal memory	
No. specimens for which numeric results saved in memory at once	most recent 100,000 results	300,000 on USB and 1,500 results on internal memory	300,000 on USB and 1,000 records with histograms on internal memory	
No. specimens for which histo/cytogram results saved in memory at once	most recent 100,000 results	300,000 on USB and 1,500 results on internal memory	300,000 on USB and 1,000 records with histograms on internal memory	
Instrument performs delta checks	yes	no	no	
Parameters for which flags may appear	morphological flags including PLT clump, left shift, blast, variant LYM, RBC fragments, more	dispersional data alerts, suspect measurand flags, and count invalidation flags	dispersional data alerts, suspect parameter flags, and count invalidation flags	
Flagging is operator selectable	operator and vendor selectable	yes	yes	
Tags and holds results for follow-up, confirmatory testing, or rerun	yes	no	no	
Parameters for flags for holding samples defined by user or vendor	user and vendor	user	user	
Scattergram display: cell-specific color	yes	no	yes	
Histogram display: color with thresholds	yes	no	yes	
User interface can display choice of specimen or result information	yes	yes	yes	
LIS interface formats supported	ASTM 1394-91, ASTM 1381, HL7	proprietary	proprietary	
Information transferred via LIS interface	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, instrument to LIS	numeric and flag results, instrument to LIS	
LOINC codes transmitted with all results/Sent in message to LIS/Listing of machine codes and corresponding LOINC for each test	no/no/no	no/no/no	no/no/no	
Interface available or planned to automated specimen-handling system	Abbott, Inpeco	no	no	
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, Interleaved 2 of 5	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	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	
Accommodates barcode placement per CLSI standard Auto02-A2	yes	no	no	
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	1 (Alinity hq module)/3 CBC/diff, 1 retic	1/2	1/2	
Time required for daily, weekly, monthly maintenance	daily: 0 (automatic) for Alinity hq, hs modules; weekly: 0 (automatic) for Alinity hq, hs modules	daily: none; weekly: ~15 min.; biannually: ~10 min.	daily: none; weekly: 15 minutes; quarterly: ~10 minutes	
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	no/no	no/no	
Manufacturer can perform diagnostics via modem	no	no	no	
Distinguishing features (supplied by company)	high productivity, scalable systems that use only 3 reagents to provide CBC results with 6-part WBC differential and nRBC; duplicate reagents onboard, automated daily and weekly maintenance; seamless connectivity to Accelerator a3600 lab automation system and AlinIQ middleware	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 icons and minimal layers	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 UNI-FLOW optical flow cytometry technology with a patented lyse allowing for clear separation of the 5 WBC populations	

†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

*refer to CELL-DYN Emerald operator's manual for warnings, limitations, and precautions

*refer to CELL-DYN Emerald 22 operator's manual for warnings, limitations, and precautions

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*
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2019/—/—	2006/2006/—	2005/2005/—
No. units installed in U.S./Outside U.S./List price†	—/—/\$75,000	>550/>2,700/\$185,000	>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 %&#	standard menu plus: MPV, RDW, retic %&#, neut %&#, mono %&#, lymph %&#, eos %&#, baso %&#	standard menu plus: MPV, RDW, retic %&#, IRF, NRBC %&#, CD61, CD3T %&#, CD4T %&#, CD8T %&#, 4/8, neut %&#, mono %&#, lymph %&#, eos %&#, baso %&#
Tests submitted for 510(k) clearance/Tests in development	—	—	—
Tests for research use only	—	—	—
Tests unique to analyzer	—	atypical depolarization flag	CD61 for PLTs, CD3/4, CD3/8 (immuno T cell)
Differential method(s) used	UNI-FLOW Optical Technology	MAPSS (multi-angle polarized scatter separation)	MAPSS (multi-angle polarized scatter separation), three-color fluorescence
Analytical measurement range:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV (fL) or Hct (%) Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes
Precision:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	neut% r=1.00, slope=0.97, y=1.88; lymph% r=0.99, slope=1.00, y=0.30; mono% r=0.92, slope=0.96, y=0.42; eos% r=0.97, slope=0.93, y=0.22; baso% r=0.63, slope=0.26, y=0.04	neut% r=0.983, slope=0.97, y=-1.98; lymph% r=0.921, slope=0.95, y=0.94; mono% r=0.711, slope=1.10, y=1.93; eos% r=0.952, slope=1.04, y=0.01; baso% r=0.146, slope=0.18, y=1.22	neut% r=0.942, slope=0.947, y=0.446; lymph% r=0.936, slope=0.943, y=2.811; mono% r=0.623, slope=1.057, y=0.851; eos% r=0.446, slope=1.024, y=0.288; baso% r=0.232, slope=0.257, y=0.350
Interfering substances:	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes
Interfering substances: differential	platelet aggregates, erythroblasts, small lymphocytes, immature cells, resistant RBCs, giant or hypersegmented neutrophils, bands	fragile WBC, neutrophil aggregates, lytic-resistant RBCs, NRBCs, PLT clumps, cryofibrinogen, cryoglobulin, paraproteins	see WBC
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	40/40	84/84	105/105
Minimum specimen volume open/Closed/Sample dead volume closed	21 µL/21 µL/500 µL	150 µL/230 µL/1.2 mL	120 µL/120 µL/0.5 mL, 0.3 mL for 10.25 × 64 mm tubes
Microsample capability	no	no	yes
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	no/—	no/—	no/—
• Slide maker stainer sold separately or combined unit	—	—	—
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/yes	yes/yes
Maximum amount of archived data accessible when system online	300,000 on USB and 1,000 records with histograms on internal memory	10,000 results	10,000 results
No. specimens for which numeric results saved in memory at once	300,000 on USB and 1,000 records with histograms on internal memory	10,000 results	10,000 results
No. specimens for which histo/cytogram results saved in memory at once	300,000 on USB and 1,000 records with histograms on internal memory	10,000 results	10,000 results
Instrument performs delta checks	no	no	yes
Parameters for which flags may appear	dispersional data alerts, suspect parameter flags, and count invalidation flags	NRBC, FWBC, NWBC, RRBC, band, IG, blast, variant lymph, RBC morph., DFLT, MCHC, LRI, URI, LURI, ATYPDEP, high-low interp. message, WBC	band, IG, blast, variant lymph, nWBC, rstRBC, IR, PLT clump, ASYM, FP, CD61 agglutination, clot detected, aspiration, short sample
Flagging is operator selectable	no	yes	yes
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	vendor	user	user
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen or result information	yes	yes	yes
LIS interface formats supported	proprietary	proprietary	ASTM 1394
Information transferred via LIS interface	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, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	no/no/no	no/no/no	no/no/no
Interface available or planned to automated specimen-handling system	no	no	no
Barcode symbologies read on specimen tube	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, UPCA, UPC E	Codabar, Code 39, Code 128, Interleaved 2 of 5, ISBT	Codabar, Code 39, Code 128, Interleaved 2 of 5
Accommodates barcode placement per CLSI standard Auto02-A2	no	no	yes
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	1/2	1/3	0/4
Time required for daily, weekly, monthly maintenance	daily: none; weekly: 15 minutes; quarterly: ~10 minutes	daily: ~30 seconds; weekly: ~5 min.; monthly: ~10 min.	daily: ~30 seconds; weekly: ~10 min.; monthly: ~5 min.
Onboard diagnostics for troubleshooting/Limited to software problems	no/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	no	yes	yes
Distinguishing features (supplied by company)	small: number of reagents used, footprint, sample size; safe, open tube sampling device; closed tube, continuous autoloading with automated rerun	touch-sensitive screen, all optical technology; onboard maintenance videos; lyse-resistant RBC mode; rules-based result annotations	4 optical and 3 fluorescent detectors provide multiple scatterplot analysis; 2D optical platelets prevent interferences; fluorescent analysis of reticulocytes, NRBCs, and 3-color monoclonal analysis; OpenFlow MAb test selections; touch-sensitive screen, interfaces to Accelerator a3600 track system
†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			
	*refer to CELL-DYN Emerald 22 Autoloader operator's manual for warnings, limitations, and precautions	*refer to CELL-DYN Ruby operator's manual for warnings, limitations, and precautions	*refer to CELL-DYN Sapphire operator's manual for warnings, limitations, and precautions

Part 3 of 13	Advanced Instruments Julie Mackenzie gloocyte@aicompanies.com Norwood, MA 781-320-9000 www.aicompanies.com	Beckman Coulter Kanchia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Kanchia Johnson kjohnson05@beckman.com Miami, FL 305-380-3800 www.beckmancoulter.com
Name of instrument	GloCyte Automated Cell Counter for CSF	DxH Connected Workcell	DxH SMS II
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2016/2018/—	2014/2014/—	2018/2018/>15
No. units installed in U.S./Outside U.S./List price†	—	100/200/\$690,000	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	—
Tests submitted for 510(k) clearance/Tests in development	—	—/immature granulocytes, body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter reticulocytes %&#, more	—
Tests for research use only	—	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	—
Tests unique to analyzer	—	extended retic panel: MRV; direct count MPV, MCV, MDW; body fluid: BAL fluids; Early Sepsis Indicator; MDW	—
Differential method(s) used	—	biophysical characterization with 5 angles of light scatter for size and refractive capabilities, direct volume, conductivity for intracellular and nuclear complexity, more	—
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	TNC: 3–123 cells/μL (reportable range, 3–6,500 cells/μL)/ 2–123 cells/μL (reportable range, 2–615,644 cells/μL) — — —	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 0.000–30.000
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	TNC: 2.5–18.0% repeatability CV/ 2.7–16.3% repeatability CV — — —	≤3.0%/≤1.5% ≤1.5%/≤3.5% ≤1.0% (MCV) —
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	—	neut= ±2.0; lymph, mono= ±3.0; eso, baso= ±1.0 or 10%, whichever is greater	—
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	possibly precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant red cells, giant platelets, platelet clumps, more very high WBC count, high concentration of very large platelets, autoagglutinins very high WBC count, high concentration of very large platelets, autoagglutinins platelet clumps, white cell fragments, very small red cells, red cell fragments, giant platelets, electronic noise severe lipemia, heparin, certain unusual RBC abnormalities that resist lysing —	none none none none none —
Interfering substances: differential	—	elevated triglycerides, precipitated elevated proteins, hypogranular granulocytes, agranular granulocytes, lyse-resistant red cells, very small or multipopulation lymphocytes	none
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	CSFs: ~12/—	300/300	140 slides/—
Minimum specimen volume open/Closed/Sample dead volume closed	60 μL/—/—	165 μL/165 μL/400 μL or 250 μL for MAP tubes	90 μL/90 μL/250–400 μL
Microsample capability	—	yes	yes
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	no/—	yes/—	yes/—
• Slide maker stainer sold separately or combined unit	—	sold separately (\$165,000)	—
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/yes	no/no
Maximum amount of archived data accessible when system online	—	up to 100,000 patient results including graphics	—
No. specimens for which numeric results saved in memory at once	>100,000 results	up to 100,000	—
No. specimens for which histo/cytogram results saved in memory at once	—	up to 100,000	—
Instrument performs delta checks	—	yes	no
Parameters for which flags may appear	control results out of range, expired reagents warning	P flag appears on slide with aspiration errors	—
Flagging is operator selectable	no	yes	—
Tags and holds results for follow-up, confirmatory testing, or rerun	yes	yes	no
Parameters for flags for holding samples defined by user or vendor	vendor	user and vendor	—
Scattergram display: cell-specific color	no	yes	no
Histogram display: color with thresholds	no	yes	no
User interface can display choice of specimen or result information	yes	yes	yes
LIS interface formats supported	RS232, bidirectional	ASTM 1394, ASTM 1238, IEEE MIB, CLSI LIS01-A2	ASTM 1394, ASTM 1238, IEEE MIB, CLSI LIS1-A, CLSI LIS2-A
Information transferred via LIS interface	numeric and flag results, instrument to LIS; patient orders, LIS to instrument—broadcast	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)	patient demographics, LIS to instrument—broadcast; host query for patient demographics and orders
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	yes/yes/—	yes/yes/yes	no/no/no
Interface available or planned to automated specimen-handling system	no	Beckman Coulter	Beckman Coulter
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, Interleaved 2 of 5, Data Matrix	Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7, ASTM	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5, NW7
Accommodates barcode placement per CLSI standard Auto02-A2	yes	yes	yes
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	0/2 (RBC and TNC reagents)	1/4	1 preloaded cube with up to 30 cleaning cycles/3 (can vary): stain, buffer, diluent
Time required for daily, weekly, monthly maintenance	minimal annual maintenance required	daily: 30 minutes; weekly: none; monthly: none	daily: up to 20 min.; weekly: up to 30 min.; monthly: as needed
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	no	yes	yes
Distinguishing features (supplied by company)	1 cell/μL limit of detection for RBC and TNC; consistent turnaround time for standardization and for Lean practices; disposable test cartridges eliminate carryover for infectious samples	Workcell has redundant power supplies, monitors, computers, and track systems for independent modular functionality if needed; workload-balancing, proprietary magnetic track system has zero daily, weekly, monthly, yearly maintenance	hemisphere technology analyzes to overcome variations in 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 on slide to note aspiration integrity gaps alerting user

†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 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	DxH 520	DxH 560 AL	DxH 690T
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 [†]	2019/2018/>300 >20/>700/\$30,000	2020/2021/>150 45/142/\$52,000	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
Tests submitted for 510(k) clearance/Tests in development Tests for research use only	— IMM %&#, LHD, MAF, PCT, PDW	— IMM %&#, LHD, MAF, PCT, PDW	—/immature granulocytes body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter, reticulocytes %&#, low hemoglobin density, more
Tests unique to analyzer	—	—	extended retic panel: MRV; direct count MPV, MCV, MDW, Early Sepsis Indicator: MDW
Differential method(s) used	optical bench with Coulter digital impedance	flow cytometry with proprietary dynamic gating	near-native biophysical cell characterization with 5 angles of light scatter for size and refractive capabilities, direct volume Coulter principle, more
Analytical measurement range:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV (fL) or Hct (%) Reticulocytes 	0.20–100.00 × 10 ³ cells/μL/0.20–8.00 × 10 ⁶ cells/μL 0.20–25.00 g/dL/7.0–2000.0 × 10 ³ cells/μL 50.0–150.0 fL (MCV) —	0.050–400.00 × 10 ³ cells/μL/0.005–8.500 × 10 ⁶ cells/μL 0.10–25.50 g/dL/3.0–3,000.0 × 10 ³ cells/μL 50.00–150.00 fL (MCV, direct measure) 0.000–30.000
Precision:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	NE, LY, MO ±3.00; EO ±1.5; BA ±1.0 or 10%, whichever is greater	NE, LY, MO ±3.00; EO ±1.5; BA ±1.0 or 10%, whichever is greater	neut ±2.0; lymph, mono ±3.0; eso and baso ±1.0 or 10%, whichever is greater
Interfering substances:	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes
Interfering substances: differential	possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells	possibly unlysed RBCs, NRBCs, cryoglobulin, cryofibrinogen, PLT clumps, giant PLTs, agglutinated white cells	possibly precipitated elevated proteins, cryoglobulin, fragmented white cells, agglutinated white cells, lyse-resistant RBCs, giant PLTs, PLT clumps, unlysed particles >35 fL
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	55 closed-tube samples, 60 open-tube samples/ 55 closed-tube samples, 60 open tube-samples	55 closed-tube samples, 60 open-tube samples/ 55 closed-tube samples, 60 open-tube samples	100/100
Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed	16.7 μL/16.7 μL/1 mL standard tube or 375 μL MAP microtainer yes no/—	16.7 μL/16.7 μL/1 mL standard tube or 375 μL MAP microtainer yes no/—	165 μL/165 μL/400 μL or 250 μL with MAP tubes yes no/—
Instrument archives patient data/Archiving is patient specific Maximum amount of archived data accessible when system online No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at once Instrument performs delta checks Parameters for which flags may appear	yes/yes 30,000 patient results 30,000 patient results 30,000 patient results — definitive range, measurement range, normal range, edited sample, low confidence result, H and H check fail, action limits, reference limits operator and vendor selectable	yes/yes 30,000 patient results 30,000 patient results 30,000 patient results 30,000 patient results no definitive range, measurement range, normal range, edited sample, low confidence result, H and H check fail, action limits, reference limits operator and vendor selectable	yes/yes up to 60,000 patient results up to 60,000 patient results up to 60,000 patient results yes 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
Flagging is operator selectable Tags and holds results for follow-up, confirmatory testing, or rerun Parameters for flags for holding samples defined by user or vendor Scattergram display: cell-specific color Histogram display: color with thresholds User interface can display choice of specimen or result information	yes user yes yes yes	yes user yes yes yes	yes user yes (3D scatter and surface plots for flow modules) yes yes
LIS interface formats supported Information transferred via LIS interface	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	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	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 orders yes/yes/yes
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	no/no/no no Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7, ISBT 128 (donor ID only)	no/no/no no Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7, ISBT 128 (donor ID only)	Beckman Coulter, Roche Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5, NW7 yes
Accommodates barcode placement per CLSI standard Auto02-A2	yes	yes	yes
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	1 preloaded bottle/2 (CBC, diff)	1 preloaded bottle/2 (CBC, diff)	1 preloaded cube with up to 30 cleaning cycles/3 (CBC, diff, retic [optional])
Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems Manufacturer can perform diagnostics via modem	daily: 5 min.; weekly: none; monthly: 15 min. yes/no no	daily: 5 min.; weekly: none; monthly: 15 min. yes/no no	daily: none (autonomous); weekly: none; monthly: none yes/no yes
Distinguishing features (supplied by company) [†] does not include slide maker stainers Note: a dash in lieu of an answer means company did not answer question or question is not applicable	small aspiration: 16.7 μL for a closed tube, 5-part 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	small aspiration: 16.7 μL for a closed tube, 5-part differential instrument, ideal for infants and difficult draws; 50 tube load and walkaway capacity; integrated touchscreen and only one external reagent	DataFusion uses real-time analytics and bypasses special modes, avoiding reruns; industry-leading accuracy, precision and low backgrounds with 93% first-pass technology; FDA-cleared Early Sepsis Indicator for early sepsis detection

Part 5 of 13	Beckman Coulter Kanochia Johnson Miami, FL 305-380-3800 www.beckmancoulter.com	Beckman Coulter Kanochia Johnson Miami, FL 305-380-3800 www.beckmancoulter.com	CellaVision Ken Childs Durham, NC 919-806-4420 www.cellavision.com
Name of instrument	DxH 800	DxH 900	CellaVision DC-1
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2008/2008/—	2018/2018/>350	2021/2019/—
No. units installed in U.S./Outside U.S./List price†	>2,000/>1,500/\$229,000	80/240/\$259,600	—
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	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	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
Tests submitted for 510(k) clearance/Tests in development	—	—/body fluid mononuclear %&#, body fluid polymorphonuclear %&#, early granulated cells %&#, high light scatter reticulocytes %&#, more	—
Tests for research use only	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	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	—
Tests unique to analyzer	—	extended retic panel: MRV; direct count MPV, MCV, MDW, Early Sepsis Indicator: MDW (when enabled)	—
Differential method(s) used	Automated Intelligent Morphology using volume, conductivity, 5 angles of light scatter, digital signal processing, advanced algorithm applications, more	near-native biophysical cell characterization with 5 angles of light scatter for size and refractive capabilities, direct volume Coulter principle, more	automated brightfield microscopy, image analysis, AI
Analytical measurement range:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV (fL) or Hct (%) Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes
Precision:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	neut= ±2.0; lymph, mono= ±3.0; eso, baso= ±1.0 or 10%, whichever is greater	neut= ±2.0; lymph, mono= ±3.0; eso, baso= ±1.0 or 10%, whichever is greater	seg neu% y = 0.9904x + 0.37; lymph% y = 0.998x + 0.12; mono% y = 0.9983x + 0.24; eos% y = 0.9912x + 0.03; baso% y = 0.9427 + 0.08
Interfering substances:	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes
Interfering substances: differential	elevated triglycerides, precipitated elevated proteins	elevated triglycerides, precipitated elevated proteins, hypogranular granulocytes, agranular granulocytes, lyse-resistant red cells, very small or multipopulation lymphocytes	—
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	>100/>90	300 samples/300 samples	—/10 slides
Minimum specimen volume open/Closed/Sample dead volume closed	165 µL/165 µL/250–400 µL	165 µL/165 µL/250–400 µL	—
Microsample capability	yes	yes	—
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	yes/—	no/—	no/—
Slide maker stainer sold separately or combined unit	—	—	sold separately
Instrument archives patient data/Archiving is patient specific	yes/no	yes/yes	yes/no
Maximum amount of archived data accessible when system online	up to 100,000 patient results including graphics	up to 100,000 patient results including graphics	unlimited
No. specimens for which numeric results saved in memory at once	up to 100,000 patient results including graphics	up to 100,000 patient results including graphics	1,500
No. specimens for which histo/cytogram results saved in memory at once	up to 100,000 patient results including graphics	up to 100,000 patient results including graphics	—
Instrument performs delta checks	yes	yes	no
Parameters for which flags may appear	flags can be created and customized for all results	—	—
Flagging is operator selectable	yes	yes	—
Tags and holds results for follow-up, confirmatory testing, or rerun	yes	yes	yes
Parameters for flags for holding samples defined by user or vendor	user and vendor	user and vendor	—
Scattergram display: cell-specific color	yes	yes (WBC, nRBC, reticulocyte)	yes, can be imported from the LIS and displayed in the user interface
Histogram display: color with thresholds	yes	yes (WBC, RBC, PLT)	—
User interface can display choice of specimen or result information	yes	yes	yes
LIS interface formats supported	CLSI LIS01-A2	CLSI LIS01-A2	ASTM 1394-91
Information transferred via LIS interface	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)	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, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	yes/yes/yes	yes/yes/yes	no/no/no
Interface available or planned to automated specimen-handling system	Beckman Coulter	Beckman Coulter	no
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, Interleaved 2 of 5, NW7	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5, NW7	Codabar, Code 39, Code 128, Interleaved 2 of 5, DataMatrix, QR
Accommodates barcode placement per CLSI standard Auto02-A2	yes	yes	no
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	1 preloaded cube with up to 30 cleaning cycles/3 (CBC/diff incl. Coulter Plt, retic, extended retic panel)	1 preloaded cube with up to 30 cleaning cycles/3 (CBC/diff incl. Coulter Plt, retic, extended retic panel)	0/0
Time required for daily, weekly, monthly maintenance	daily: none (autonomous); weekly: none; monthly: none	—	daily: none; weekly: 5 min.
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes	yes	no
Distinguishing features (supplied by company)	Automated Intelligent Morphology provides 3 independent counts for RBC, WBC, PLT; blast flagging by cell lineage; reliable MPV and reliable hemoglobin with few interferences; 48–72 hour sample stability on CBC parameters	DataFusion uses real-time analytics and bypasses special modes, avoiding reruns; platelets achieve industry-leading accuracy, precision, and low backgrounds with first-pass technology; near-native state RBC analysis throughout the maturation cycle for direct read and accurate indices	network use allows remote review of blood smears and linking of multiple CellaVision analyzers in multiple locations; WBC and other nucleated cells classified into 18 categories; RBC morphology characterized for 6 categories; leverages high-speed robotics and digital imaging to automatically locate and capture high-quality images of cells

†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 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	CellaVision DM9600/DM1200	Medonic M-Series	Abacus 3CP
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2004/2003/—	2006/—/—	2013/2013/—
No. units installed in U.S./Outside U.S./List price†	—/—/~\$135,000–\$175,000	>2,000/>25,000/—	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, platelet clumps, erythroblasts, more	WBC, RBC, HGB, Hct, MCV, MCH, MCHC, PLT, gran %&#, mid, lymph, RDW, MPV	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, mono, lymph, RDW%, MPV, GRA %&#
Tests submitted for 510(k) clearance/Tests in development	—	—	—
Tests for research use only	—	—	—
Tests unique to analyzer	analysis of cytocentrifuged samples, body fluids (reported parameters: neutrophils, eosinophils, lymphocytes, macrophages, including monocytes), other (basophils, lymphoma cells, atypical lymphocytes, blast cells, tumor cells)	micropipette adaptor for capillary sampling	—
Differential method(s) used	light microscopy, image analysis, artificial neural networks	impedance	volumetric impedance method, light absorbance for HGB measurement
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	0.5–80.0/0.5–7.00 2.0–23.0/30–1,800	0.95–83.45/0.44–7.74 1.4–23.7/11–975
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	7.0 × 10 ⁹ /L, ≤1.8% (OT CV)/4.59 × 10 ¹² /L, ≤0.9% (OT CV) 14.3 g/dL, ≤0.8% (OT CV)/239 × 10 ⁹ /L, ≤3.0% (OT CV) MCV: 86.8 fL/≤0.5% (OT CV)	<2.7%/<1.7% <2.0%/<6% <1.7% (MCV and Hct)
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	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	—	—
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	NRBCs, unlysed RBCs, hemolysis, leukemias, chemotherapy, cryoglobulins, multiple myeloma, lymphocyte count interference leukocytosis with concurrent anemia, agglutinated RBCs, cold agglutinins red blood cell agglutination, WBC, thrombocytosis microcytosis, agglutinated RBCs, giant platelets in excessive numbers, chemotherapy, hemolysis, ACD blood, RBC inclusions, platelet agglutination unlysed RBCs, leukocytosis, lipemia, hyperproteinemia, hyperbilirubinemia, fetal blood	>5 NRBCs/100 WBCs, PLT clumps, large PLTs WBC count >50.0 × 10 ³ /μL WBC count >50.0 × 10 ³ /μL PLT clumps/large PLTs WBC count >50.0 × 10 ³ /μL, lipids >270 mg/dL
Interfering substances: differential	—	factors that affect WBC plus: large lymphocytes, atypical lymphocytes, blasts, basophils in excessive numbers, metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells in excessive numbers	>5 NRBCs/100 WBCs, PLT clumps, large PLTs
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	—/35 differentials	>60/>60	60/60
Minimum specimen volume open/Closed/Sample dead volume closed	—	<110 μL/<250 μL/1 mL	100 μL/100 μL/—
Microsample capability	—	yes	no
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	—	no/—	no/—
• Slide maker stainer sold separately or combined unit	—	—	—
Instrument archives patient data/Archiving is patient specific	yes/no	no/no	yes/no
Maximum amount of archived data accessible when system online	unlimited	—	10,000 results
No. specimens for which numeric results saved in memory at once	~4,000	>1,000 samples	10,000 results
No. specimens for which histo/cytogram results saved in memory at once	—	>1,000 samples	10,000 results
Instrument performs delta checks	no	no	no
Parameters for which flags may appear	—	—	range flags, measurement condition flags, parameter warning, error flags
Flagging is operator selectable	—	yes	no
Tags and holds results for follow-up, confirmatory testing, or rerun	—	no	yes
Parameters for flags for holding samples defined by user or vendor	—	user	vendor
Scattergram display: cell-specific color	—	no	no
Histogram display: color with thresholds	—	yes	yes
User interface can display choice of specimen or result information	—	yes	no
LIS interface formats supported	ASTM 1394	through middleware	HL7, Diatron Serial Communication
Information transferred via LIS interface	numeric and flag results, 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	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	no/no/yes (for peripheral blood)	no/no/no	no/no/no
Interface available or planned to automated specimen-handling system	—	—	no
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, Interleaved 2 of 5, QR, DataMatrix	—	Codabar, Code 39, Code 128, Interleaved 2 of 5
Accommodates barcode placement per CLSI standard Auto02-A2	—	yes	no
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	none/1	1/2	1/3
Time required for daily, weekly, monthly maintenance	daily: none; weekly: 5 minutes	daily: <2 minutes; monthly: 10 minutes; 6 months: 75 minutes	daily: 10 minutes; weekly: 15 minutes; monthly: 10 minutes
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	no/no
Manufacturer can perform diagnostics via modem	no	no	no
Distinguishing features (supplied by company)	fully automated slide handling and oiling available in 2 models; performs peripheral blood and body fluid differentials; WBC and other nucleated cells classified into 18 categories; RBC morphology characterized for 22 categories; network use allows remote review of blood smears and linking of multiple analyzers in multiple locations	micropipette adaptor for capillary sampling; 3-part diff with auto sampling capability; no weekly maintenance	reliable 3-part diff analyzers with 2 sampling modes (cap-piercing mode for closed-tube sampling and another for open tubes); operator safety: self-cleaning procedures minimize daily maintenance; user-friendly, easy-to-operate, high-resolution touchscreen; USB and barcode option to load QC target values; capable of reading QR codes for reference input data; confidence: system uses easy-to-understand warning messages and sample flags, employs a comprehensive QC SW package
†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 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	Abacus 5	Pentra XLR	Pentra 60C+ Hematology Analyzer
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2013/2009/—	2016/2015/—	2000/2000/—
No. units installed in U.S./Outside U.S./List price†	35/3,120/\$31,850	—/—/\$77,500	>350/>600/\$47,313
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	standard menu plus: RDW-SD, RDW-CV, MPV	standard menu plus: retic %&#, IRF%, CRC%	standard menu plus: RDW, MPV
Tests submitted for 510(k) clearance/Tests in development	—	—	—
Tests for research use only	—	PCT, PDW, ATL, LIC	PCT, PDW, ATL, LIC
Tests unique to analyzer	—	automatic dilution for over-range WBC and platelet	—
Differential method(s) used	laser light scatter technology, impedance method, light absorbance	DHSS technology combining cytochemistry, focused flow impedance, light absorbance	DHSS technology combining cytochemistry, focused flow impedance, light absorbance principles of measurement
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	—	—	neut% r=0.99, lymph% r=0.98, mono% r=0.96, eos% r=0.89, baso% r=0.54
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes
Interfering substances: differential	>5 NRBCs/100 WBCs, PLT clumps, large PLTs	NRBCs, PLT clumps, lyse-resistant RBCs	NRBCs, PLT clumps, lyse-resistant RBCs
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	60/60	80/80	60/60
Minimum specimen volume open/Closed/Sample dead volume closed	110 µL/110 µL/—	30 µL for CBC, 53 µL for CBC and differential, 35 µL for reticulocyte/100 µL/—	30 µL for CBC, 53 µL for CBC and differential/30 µL for CBC and 53 µL for CBC and differential/—
Microsample capability	no	yes	yes
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	no/—	no/—	no/—
• Slide maker stainer sold separately or combined unit	—	—	—
Instrument archives patient data/Archiving is patient specific	yes/no	yes/yes	yes/yes
Maximum amount of archived data accessible when system online	100,000 results	10,000 sample results with graphics and numerical data	10,000 sample results with graphics and numerical data
No. specimens for which numeric results saved in memory at once	100,000 results	unlimited with backup	unlimited with backup
No. specimens for which histo/cytogram results saved in memory at once	100,000 results	unlimited with backup	unlimited with backup
Instrument performs delta checks	no	yes	no
Parameters for which flags may appear	pathological flags, lab limits (normal ranges), reagents alert, instrument alerts	all CBC and diff parameters have flags	all CBC and diff parameters have flags
Flagging is operator selectable	no	no	no
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	vendor	vendor	vendor
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen or result information	no	no	no
LIS interface formats supported	HL7, Diatron Serial Protocol	proprietary, ASTM 1394, HL7	ASTM 1394 and 1238, HL7
Information transferred via LIS interface	histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, patient orders, LIS to instrument—broadcast; host query for patient demographics and orders	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, LIS to instrument—broadcast
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	no/no/no	no/no/no	no/no/no
Interface available or planned to automated specimen-handling system	no	no	no
Barcode symbologies read on specimen 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 per CLSI standard Auto02-A2	yes	yes	yes
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	1/3	2/6	2/5
Time required for daily, weekly, monthly maintenance	daily: 10 minutes; weekly: 15 minutes; monthly: 10 minutes	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes
Onboard diagnostics for troubleshooting/Limited to software problems	no/no	yes/yes	yes/yes
Manufacturer can perform diagnostics via modem	no	no	yes, with Data Manager
Distinguishing features (supplied by company)	compact, benchtop 5-part laser WBC differential analyzer provides accurate and precise results; 2 sampling modes (cap-piercing mode for closed-tube sampling and another for open tubes); field upgradeable with optional autosampler with built-in barcode reader; sample capacity: 100 tubes; user friendly and easy to operate: easy-to-follow, intuitive icon user interface	customized dilution ratio for over-range WBC up to $360 \times 10^3/\text{mm}^3$ and platelet up to $5,600 \times 10^3/\text{mm}^3$; auto rerun of patient results based on customized criteria; autovalidation of patient results based on customized criteria; can connect to Lite ^{DM} Patient Data Manager, which interfaces with third-party medical devices	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 ^{DM} Patient Data Manager, which interfaces with third-party medical devices

†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 Susan Behnke susan.behnke@horiba.com Irvine, CA 888-903-5001 ext. 4553 www.horiba.com/us/en/medical	Mindray Anna Chen a.chen@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com	Mindray Anna Chen a.chen@mindray.com Redmond, WA 425-881-0361 ext. 3305 www.mindraynorthamerica.com	
Name of instrument	Pentra XL 80	BC-5390	BC-3600	
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2004/2003/—	2016/2012/—	2015/2011/—	
No. units installed in U.S./Outside U.S./List price [†]	>250/>900/\$76,808	24/1,612/—	78/4,120/—	
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	standard menu plus: automatic dilution of over-range results (WBC × 3, RBC/Hgb/PLT × 2), RDW, MPV	standard menu plus: RDW-CV, RDW-SD, MPV, mono %&#, lymph %&#, eos %&#, baso %&#	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, gran %&#, lymph %&#, mid %&#, MPV, RDW	
Tests submitted for 510(k) clearance/Tests in development	—	—	none/none	
Tests for research use only	PCT, PDW, ATL, LIC	—	none	
Tests unique to analyzer	automatic dilution protocol	—	none	
Differential method(s) used	DHSS technology combining cytochemistry, focused flow impedance, light absorbance	flow cytometry, light scatter	impedance method for WBC, RBC, MCV, RDW, PLT, MPV and WBC 3-part differential determination, colorimetric method for HGB determination	
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	0–120/0–8 0–24/0–1,900 (>2 g/dL Hb) 0–2,800 (<2 g/dL Hb), 0–67% (Hct) —	0.3–200/0.2–8.0 0.5–25/5–2,000 2–75% (Hct) —	
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<2%/<2% <1%/<5% <2% (Hct) —	<0.15 (SD) or 3.0% (CV)/<1.5% <1.5%/<7.5 (SD) or 5% (CV) <1.5% (MCV) —	
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	neut% r=0.99, lymph% r=0.98, mono% r=0.96, eos% r=0.89, baso% r=0.54	neut%: ±5.00 or ±10.0%; lym%: ±4.00 or ±10.0%; mon%: ±3.00 or ±10.0%; eos%: ±2.00 or ±10.0%; bas%: ±1.00 or ±10.0%	—	
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	NRBCs, PLT clumps, lyse-resistant RBCs cold agglutinins Hct: extreme leukocytosis microcytes, PLT clumps extreme lipemia, leukocytosis —	platelet aggregation, lyse-resistant erythrocytes, erythroblasts, cold agglutinin, cryoglobulin, giant platelets, lipemia, chylomicronemia cold agglutinin, fragmented erythrocytes, leukocytosis, giant platelets RBC fragments, very high WBC count, high concentration of very large platelets, microclots, RBC rouleaux or agglutinates (autoagglutination) PLT aggregation or PLT satellitism, giant platelets, microcytosis, fragmented erythrocytes leukocytosis, lipemia, chylomicronemia, abnormal protein —	certain unusual RBC abnormalities that resist lysing, nucleated RBCs, fragmented WBCs, unlysed particles, very large or aggregated platelets very high WBC count, high concentration of very large platelets, agglutinated RBCs and smaller RBC very high WBC count, high concentration of very large platelets, agglutinated RBCs, RBC fragments 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 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 —
Interfering substances: differential	NRBCs, lyse-resistant RBCs, extreme hyperbilirubinemia	lysis-resistant RBC, NRBC, PLT aggregates, giant PLT	known factors that affect the WBC count as listed above, high triglycerides that can affect lysing	
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	80/80	60/60	60/60	
Minimum specimen volume open/Closed/Sample dead volume closed	30 µL for CBC/53 µL for CBC and differential/0.5 mL	100 µL/33 µL, predilute 20 µL/1 mL	100 µL/21 µL, predilute 20 µL/1 mL	
Microsample capability	yes	yes	yes	
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	no/—	no/—	no/—	
• Slide maker stainer sold separately or combined unit	—	—	—	
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/yes	no/no	
Maximum amount of archived data accessible when system online	10,000 sample results with graphics and numerical data	100,000 results	40,000 results	
No. specimens for which numeric results saved in memory at once	unlimited with backup	100,000	40,000	
No. specimens for which histo/cytogram results saved in memory at once	unlimited with backup	100,000	40,000	
Instrument performs delta checks	yes	yes	no	
Parameters for which flags may appear	all CBC and diff parameters have flags	immature gran? Abn/atypical lym? RBC agglutination? iron deficiency? PLT clump? NRBC? blasts? RBC lyse resist? leukocytosis, leukopenia, anemia, anisocytosis, more operator and vendor selectable	—	
Flagging is operator selectable	no	yes	no	
Tags and holds results for follow-up, confirmatory testing, or rerun	yes	yes	no	
Parameters for flags for holding samples defined by user or vendor	vendor	—	—	
Scattergram display: cell-specific color	yes	yes	no	
Histogram display: color with thresholds	yes	yes	yes	
User interface can display choice of specimen or result information	no	yes	no	
LIS interface formats supported	proprietary, ASTM 1394 and 1238, HL7	HL7	HL7	
Information transferred via LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for patient demographics and orders	numeric and flag results, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast	
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	no/no/no	yes/yes/yes	yes/yes/no	
Interface available or planned to automated specimen-handling system	no	none	—	
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5	Codabar, Code 39, Code 93, Code 128, Interleaved 2 of 5, UPC/EAN	Codabar, Code 39, Code 128	
Accommodates barcode placement per CLSI standard Auto02-A2	yes	—	—	
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	2/5	1/4	1/4	
Time required for daily, weekly, monthly maintenance	daily: 10 minutes; weekly: 15 minutes; monthly: 15 minutes	daily: <10 minutes	daily: <10 minutes	
Onboard diagnostics for troubleshooting/Limited to software problems	no/yes	yes/no	yes/no	
Manufacturer can perform diagnostics via modem	no	yes	no	
Distinguishing features (supplied by company)	compact 5-part differential instrument with autoloader and autodilution capability, auto rerun feature, autovalidation; can connect to Lite ^{DM} Patient Data Manager, which interfaces with third-party medical devices	60 QC files; maximum 40 samples autoloader capacity, sample adaptors for pediatric and predilution samples; operation software with built-in data-management functions, 3 modes of operation: autoloader and opened and closed tube; customizable patient reports; only 1 maintenance reagent	10.4-inch all-in-one Glance color touchscreen, touch-button maintenance procedures, and low sample requirement; 40,000 patient results storage, close-tube sampling, open-tube sampling for pediatric samples; 3 types of sample adaptors, barcoded reagent, and 5 minutes daily start-up and maintenance	
[†] 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 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	HemoScreen	Advia 360 Hematology System	Advia 560/560AL Hematology System
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2018/2016/—	2015/2015/—	2015/2015/—
No. units installed in U.S./Outside U.S./List price [†]	—	—	—
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	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 submitted for 510(k) clearance/Tests in development	—	—	—
Tests for research use only	—	—	—
Tests unique to analyzer	—	—	—
Differential method(s) used	digital microscopy and computer-vision algorithms	volumetric impedance change for WBC, RBC, PLT; lytic reagents with impedance method for 3 subpopulations; spectrophotometry for HGB	volumetric impedance change for WBC, RBC, PLT; light 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 × 10 ³ /μL/1.0–8.8 × 10 ⁶ /μL	0.0–85.0/0.0–8.0	0.20–100.0/0.36–7.19
• Hemoglobin/Platelet	3.0–25.0 g/dL/20–800 × 10 ³ /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	—	—	—
Precision:			
• WBC count/RBC count	4.0%/1.5%	<4.0%/<2.5%	<3.4%/<2.0%
• Hemoglobin/Platelet	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 compared with manual differential (per CLSI H20-A2)	—	—	—
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 × 10 ³ /μL	WBC count >75.0 × 10 ³ /μL
• MCV or Hct	no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides	WBC count >75.0 × 10 ³ /μL	WBC count >75.0 × 10 ³ /μL
• Platelet	no significant interference up to 30 mg/dL bilirubin, 729 mg/dL triglycerides	PLT clumps, large PLTs	PLT clumps, large PLTs
• Hemoglobin	no significant interference up to 50 mg/dL bilirubin, 729 mg/dL triglycerides	WBC count >75.0 × 10 ³ /μL, lipids >280 mg/dL	WBC count >75.0 × 10 ³ /μL, lipids >280 mg/dL
• Reticulocytes	—	—	—
Interfering substances: differential	—	> 5 NRBCs/100 WBCs, PLT clumps, large PLTs	> 5 NRBCs/100 WBCs, PLT clumps, large PLTs
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	20/10	60/60	60/60
Minimum specimen volume open/Closed/Sample dead volume closed	40 μL/40 μL/—	100 μL/100 μL/—	100 μL/100 μL/—
Microsample capability	yes	no	yes
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	no/—	no/—	no/—
• Slide maker stainer sold separately or combined unit	—	sold separately	sold separately
Instrument archives patient data/Archiving is patient specific	yes/no	yes/no	yes/no
Maximum amount of archived data accessible when system online	1,000	100,000 results	100,000 results
No. specimens for which numeric results saved in memory at once	1,000	100,000	100,000
No. specimens for which histo/cytogram results saved in memory at once	—	100,000	100,000
Instrument performs delta checks	no	yes	yes
Parameters for which flags may appear	all CBC and differential parameters have flags; pathological flags, range flags, measurement condition flags, parameter warning, error flags	out-of-range flags, measurement condition flags (warnings); flagging on WBC and HGB channels; flagging on RBC/PLT channel/warning flags of differential parameters	pathological (diagnostic) flags; lab limits (normal 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, confirmatory testing, or rerun	no	yes	yes
Parameters for flags for holding samples defined by user or vendor	vendor	user	user
Scattergram display: cell-specific color	no	yes	yes
Histogram display: color with thresholds	no	yes	yes
User interface can display choice of specimen or result information	yes	yes	yes
LIS interface formats supported	HL7, POCT-1A	proprietary	proprietary
Information transferred via LIS interface	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 results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	yes/yes/yes	yes/yes/yes	yes/yes/yes
Interface available or planned to automated specimen-handling system	no	no	no
Barcode symbologies read on specimen 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 per CLSI standard Auto02-A2	—	no	no
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	0/0	1/3	1/3
Time required for daily, weekly, monthly maintenance	none	daily: automated; weekly: 15–20 minutes	daily: automated; weekly: 15–20 minutes
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	no/no
Manufacturer can perform diagnostics via modem	yes	yes	yes
Distinguishing features (supplied by company)	cartridge-based 5-part differential CBC analyzer FDA-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	measures 16 parameters including 3-part WBC differential; efficient manual sampling of open and closed tubes; 60 samples per hour, volume as low as 100 μL	60 samples per hour, volume as low as 110 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

[†]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 Sheryl Kirk sheryl.kirk@siemens-healthineers.com Tarrytown, NY 469-390-7319 siemens-healthineers.com/hematology	Sight Diagnostics Kevin Lee sales-us@sightdx.com Brooklyn, NY www.sightdx.com/us	Sysmex America Madeline Dintelman communications@sysmex.com Lincolnshire, IL 800-379-7639 www.sysmex.com/us	
Name of instrument	Advia 2120i Hematology System	Sight OLO	pochH-100i	
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2008/2008/—	2019/2018/—	2004/2003/—	
No. units installed in U.S./Outside U.S./List price†	698/3,900/\$245,700	—	>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 classification flags, more	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	
Tests submitted for 510(k) clearance/Tests in development	—/sepsis, MPC, MPM	—	—	
Tests for research use only	IRF, CSF eos, MPC, MPM, PCDW, PCT, PDW, PLT N, PLT X, PLT Y, PMDW, P count–2D, R count–2D, RBC Count–2D, RtcPlts%, RtcPltsCount, RtcPltsThreshold, RtcPlt Vi, more	—	—	
Tests unique to analyzer	chartable RBC morphology, large PLT enumeration, CHR, CHCM, HDW, CHDW, CHCMr, CHg, MPC, MPM, CSF: WBC, RBC, PMN, MN, neut, lymph, mono	—	absolute neutrophil count	
Differential method(s) used	peroxidase WBC: peroxidase cytochem. staining with light scatter and absorption; baso: cytochem. stripping with 2-angle laser light scatter	digital microscopy and computer-vision algorithms	direct current	
Analytical measurement range:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV (fL) or Hct (%) Reticulocytes 	0.02–400 × 10 ³ /μL/0–7.0 × 10 ⁶ /μL 0–22.5 g/dL/5–3,500 × 10 ³ /μL 30–180 (MCV) 0.2–24.5%	0.18–100.13 10 ³ /μL/1.22–7.55 10 ⁶ /μL 4.0–21.75 g/dL/18–1,028.5 10 ³ /μL 15.2–63.7% (Hct)	
Precision:	<ul style="list-style-type: none"> WBC count/RBC count Hemoglobin/Platelet MCV or Hct Reticulocytes 	2.7%/1.2% 0.93%/2.93% 0.78% (MCV) —	4.1%/2.1% 1.9%/4.8% 2.2% (Hct) —	
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	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	—	neut% r=0.98, lymph% r=0.99, MXD% r=0.75, neut# r=1.00, lymph# r=1.00, MXD# r=0.90	
Interfering substances:	<ul style="list-style-type: none"> WBC RBC MCV or Hct Platelet Hemoglobin Reticulocytes 	<ul style="list-style-type: none"> incomplete RBC lysis (peroxidase only) cold agglutinins, extreme sickle cell — — extreme lipemia, high WBC, extremely high bilirubin; colorimetric: none with cellular Hgb — 	<ul style="list-style-type: none"> monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more — 	<ul style="list-style-type: none"> lyse-resistant RBCs, cold agglutinins, cryoglobulins, PLT aggregation, NRBCs cold agglutinins, severe microcytosis, fragmented RBCs cold agglutinins, fragmented RBCs, leukocytosis (>100,000/μL) PLT aggregation, giant PLTs, microcytic RBCs, fragmented RBCs severe lipemia, abnormal protein, leukocytosis (>100,000/μL) —
Interfering substances: differential	incomplete RBC lysis, complete myeloperoxidase deficiency	monoclonal gammopathies, lipemia, chylemia, hyperbilirubinemia, sulfhemoglobinemia, methemoglobinemia, carboxyhemoglobinemia, more	—	
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	120/120	5/5	30/30	
Minimum specimen volume open/Closed/Sample dead volume closed	175 μL/175 μL/<300 μL (tube-size dependent)	~30 μL/—/—	15 μL/15 μL/15 μL	
Microsample capability	yes	yes	yes	
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	yes/—	no/—	no/—	
Slide maker stainer sold separately or combined unit	sold separately (\$107,016)	—	—	
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/no	yes/yes	
Maximum amount of archived data accessible when system online	10,000 patient results, incl. graphics	50,000 results	100 samples	
No. specimens for which numeric results saved in memory at once	10,000 patient results, incl. graphics	50,000	100 samples	
No. specimens for which histo/cytogram results saved in memory at once	10,000 patient results, incl. graphics	—	100 samples	
Instrument performs delta checks	yes	no	yes	
Parameters for which flags may appear	left shift, atypical lymphocytes, blasts, immature grans, myeloperoxidase deficiency, aniso, micro, macro, Hgb variation, hypo, hyper, NRBC, RBC fragments, RBC, more	IG, blasts, atypical LYM, nRBCs, PLT clumps, giant PLT, RBC agglutination, high reticulocytes, low reticulocytes, WBC agglutination, dual RBC population, more	flagging system suggests sample error for WBC, RBC, PLT parameters	
Flagging is operator selectable	operator and vendor selectable	no	no	
Tags and holds results for follow-up, confirmatory testing, or rerun	yes	no	no	
Parameters for flags for holding samples defined by user or vendor	user	vendor	vendor	
Scattergram display: cell-specific color	yes	no	no	
Histogram display: color with thresholds	yes	no	yes	
User interface can display choice of specimen or result information	yes	yes	yes	
LIS interface formats supported	proprietary, ASTM 1394-91, ASTM 1238-95, ASTM 1381, Atellica Data Manager provides HL7 compatibility	HL7	RS-232C	
Information transferred via LIS interface	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, instrument to LIS	numeric and flag results, histograms and scatterplots, patient demographics, orders, host query for patient demographics and orders	
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	no/no/yes	no/no/no	no/no/yes	
Interface available or planned to automated specimen-handling system	Siemens, Sysmex	none	—	
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, ASTM, Interleaved 2 of 5, JAN (8 and 13), ISBT 128	Codabar, Code 39, Code 128, Interleaved 2 of 5, QR	Code 39, Code 128, ASTM, ITF, NW7, JAN-8, JAN-13	
Accommodates barcode placement per CLSI standard Auto02-A2	yes	—	no	
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	5/3	0/0	1/2	
Time required for daily, weekly, monthly maintenance	daily: none; weekly: automated wash sequence; monthly: 15 minutes	daily: none; weekly: none; monthly: none	daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes	
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no	
Manufacturer can perform diagnostics via modem	yes	yes	yes	
Distinguishing features (supplied by company)	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 eliminates interference from RBC fragments and inclusion of large PLTs	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 user calibration, external reagents management, or routine maintenance; minimal training required, touchscreen instructions, automatic internal QC and fail-safe system	hydrodynamic focusing, automatic floating discriminators, ISBT-compliant, data-masking software for blood donor centers; optional upgrade to pochI Plus or pochI Linc available (data manager and small LIS); ability to directly link to EMR	
†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 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	XN-330, XN-430, XN-530	XN-350, XN-450, XN-550	XN-1000 Series
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2017/2016/—	2017/2015/—	2012/2011/>175
No. units installed in U.S./Outside U.S./List price†	>650/—/\$71,000–\$106,000	>1,450/>3,200/\$75,000–\$110,000	>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	standard menu plus: IG %&#, MPV, RDW-CV, RDW-SD	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 %&#
Tests submitted for 510(k) clearance/Tests in development	—	—	—
Tests for research use only	—	—	—
Tests unique to analyzer	immature granulocyte on every sample; models available through authorized distributors for POL and clinic market	immature granulocyte on every sample, optional reticulocyte and body fluid licenses available	IG %&#, PLT-F, IPF, RET-He; body fluids: two-part differential MN %&#, PMN %&#
Differential method(s) used	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	—	—	—
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes
Interfering substances: differential	—	—	—
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	60/60	60/60	100/100
Minimum specimen volume open/Closed/Sample dead volume closed	25 µL/25 µL/1 mL	25 µL/25 µL/1 mL	88 µL/88 µL/1 mL
Microsample capability	yes	yes	yes
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	no/—	no/—	no/—
• Slide maker stainer sold separately or combined unit	—	—	sold separately (\$180,950)
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/yes	yes/yes
Maximum amount of archived data accessible when system online	10,000 patient results	100,000 patient results	100,000 samples
No. specimens for which numeric results saved in memory at once	10,000	100,000	100,000
No. specimens for which histo/cytogram results saved in memory at once	10,000	100,000	100,000
Instrument performs delta checks	yes	yes	yes
Parameters for which flags may appear	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	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	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
Flagging is operator selectable	operator and vendor selectable	—	yes
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
Scattergram display: cell-specific color	yes	yes	yes
Histogram display: color with thresholds	yes	yes	yes
User interface can display choice of specimen or result information	yes	yes	yes
LIS interface formats supported	XN series ASTM 1381-95/ASTM 1894-97 or XN series ASTM 1381-02/ASTM 1894-97	XN series ASTM 1381-95/ASTM 1894-97 or XN series ASTM 1381-02/ASTM 1894-97	ASTM 1394-91, HL7
Information transferred via LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	yes/yes/no	yes/yes/no	no/no/yes
Interface available or planned to automated specimen-handling system	no	no	no
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC	Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC	Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC
Accommodates barcode placement per CLSI standard Auto02-A2	yes	yes	yes
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	1/4	1/4	1/5 cubitainer reagents, 4 fluorescent dye cartridges
Time required for daily, weekly, monthly maintenance	daily: 2 minutes; weekly: 15 minutes	daily: 2 minutes; weekly: 15 minutes	daily: <1 minute (operator time)
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	yes/no
Manufacturer can perform diagnostics via modem	yes	yes	yes
Distinguishing features (supplied by company)	6-part WBC differential including immature granulocyte 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	6-part WBC differential including immature granulocyte 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 all models	reportable parameters include IG %&#, RET-He, fluorescent PLT, body fluid with 2-part differential; onboard preloaded decision rules including automated rerun-reflex capabilities; optional wagons for complete reagent management; compatible with optional RU-20 reagent unit that allows for use of concentrated Cellpack

†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

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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-2000 Series 2012/2011/>95 >1,000/>450/\$402,667	XN-3100 Series 2017/2017/>60 >500/>25/\$562,667 (includes slide maker stainer)	XN-9100 Series 2017/2017/50 >500/>50/varies based on configuration
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, lymph, eos, baso)	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 %&#	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 %&#	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 %&#
Tests submitted for 510(k) clearance/Tests in development Tests for research use only Tests unique to analyzer	— — IG %&#, PLT-F, IPF, RET-He; body fluids: two-part differential MN %&#, PMN %&#	— — IG %&#, PLT-F, IPF, RET-He; body fluids: two-part differential MN %&#, PMN %&#	— — IG %&#, PLT-F, IPF, RET-He; body fluids: 2-part differential MN %&#, PMN %&#
Differential method(s) used	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	—	—	—
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes
Interfering substances: differential	—	—	—
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour Minimum specimen volume open/Closed/Sample dead volume closed Microsample capability Instrument prepares microscope slides automatically/No. of automatic slide makers installed • Slide maker stainer sold separately or combined unit	200/200 88 µL/88 µL/1 mL yes no/— sold separately (\$180,950)	varies by configuration/varies by configuration 88 µL/88 µL/1 mL yes yes/1 sold as combined unit	>100, varies by configuration/>100, varies by configuration 88 µL/88 µL/1 mL yes yes/configurable sold separately (\$180,950) or combined
Instrument archives patient data/Archiving is patient specific Maximum amount of archived data accessible when system online No. specimens for which numeric results saved in memory at once No. specimens for which histo/cytogram results saved in memory at once Instrument performs delta checks Parameters for which flags may appear	yes/yes 100,000 samples 100,000 100,000 yes abnormal (user-defined ex: neutrophilia, anisocytosis) and/or suspect (analyzer-generated ex: left shift?, PLT clumps?) flags all reportable parameters deemed abnormal per lab's protocol, more	yes/yes 100,000 samples 100,000 100,000 yes 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	yes/yes 100,000 samples 100,000 100,000 yes 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
Flagging is operator selectable Tags and holds results for follow-up, confirmatory testing, or rerun Parameters for flags for holding samples defined by user or vendor Scattergram display: cell-specific color Histogram display: color with thresholds User interface can display choice of specimen or result information	yes yes user and vendor yes yes yes	yes yes user and vendor yes yes yes	yes yes user and vendor yes yes yes
LIS interface formats supported Information transferred via LIS interface	ASTM 1394-91, HL7 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	ASTM 1394-91, HL7 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	ASTM 1394-91, HL7 numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders
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	no/no/yes no Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC yes	no Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC yes	Abbott, Ortho Clinical, Roche, Siemens, Beckman Coulter Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC yes
Accommodates barcode placement per CLSI standard Auto02-A2	yes	yes	yes
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required Time required for daily, weekly, monthly maintenance Onboard diagnostics for troubleshooting/Limited to software problems Manufacturer can perform diagnostics via modem	1/5 cubitainer reagents, 4 fluorescent dye cartridges daily: <1 minute (operator time) yes/no yes	1/5 cubitainer reagents, 4 fluorescent dye cartridges <3 minutes (operator time), ~15 minutes (analyzer time) yes/no yes	1/5 cubitainer reagents, 4 fluorescent dye cartridges <3 minutes (operator time), ~15 minutes (analyzer time) yes/no yes
Distinguishing features (supplied by company)	fully integrated co-primary hematology solution consisting of 2 analytical modules connected with a single sampler, providing maximum productivity and efficiency with workload balancing; reportable parameters include IG %&#, RET-He, fluorescent PLT, body fluid with 2-part differential, onboard preloaded decision rules including automated rerun-reflex capabilities; optional wagons for complete reagent management; compatible with optional RU-20 reagent unit that allows for use of concentrated Cellpack	co-primary hematology solution: 2 analytical modules plus a fully integrated 5th-generation slidemaker/stainer (SP-50); integration of the DI-60 automated cell image system, providing preclassification for WBC, RBC, and PLT estimates; compatible with optional RU-20 reagent unit that allows for use of concentrated Cellpack; optional configuration (XN-20) possesses the white cell precursor channel (WPC), which differentiates a single flag (blast/abnormal lymphocytes) into 2 distinct flags (blasts and abnormal lymphocytes)	scalable, modular system that can be configured as an island of automation or connected to TLA systems; integration of the DI-60 automated cell image system providing preclassification for WBC, RBC, and PLT estimates; tube sorter/archiver (TS-10) and A1c testing (Bio-Rad Variant II Turbo Link) provide complete testing efficiencies; optional configuration (XN-20) possesses the 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 <i>Note: a dash in lieu of an answer means company did not answer question or question is not applicable</i>			

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Name of instrument	XN-V Series*	XP-300	XW-100
First year installed in U.S./Outside U.S./No. of units sold Sept. 2021–Aug. 2022	2017/2017/10	2013/2013/—	2018/—/—
No. units installed in U.S./Outside U.S./List price†	35/28/varies by configuration	>1,400/>1,000/\$28,405	250/—/\$6,500
Menu of chartable tests (standard menu: WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, neut %&#, mono, 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 %&#	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, neut %&#, lymph %&#, MXD %&# (mono, eos, baso), RDW-SD, RDW-CV, MPV	WBC, RBC, HGB, HCT, MCV, PLT, other WBC %&#, LYM %&#, NEUT %&#
Tests submitted for 510(k) clearance/Tests in development	—	—	—
Tests for research use only	not FDA cleared for human use; for research use only	—	—
Tests unique to analyzer	PLT-F, PLT-O, IPF, RET-He; body fluids: 2-part differential MN %&#, PMN %&#	absolute neutrophil count	direct current with hydrodynamic focusing for all parameters except hemoglobin, which is measured photometrically
Differential method(s) used	fluorescent flow cytometry with side fluorescent light, forward-scattered and side-scattered light	direct current	adaptive cluster analysis
Analytical measurement range:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV (fL) or Hct (%) • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Precision:	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes 	<ul style="list-style-type: none"> • WBC count/RBC count • Hemoglobin/Platelet • MCV or Hct • Reticulocytes
Accuracy of automated differential compared with manual differential (per CLSI H20-A2)	—	neut% r=0.98, lymph% r=0.99, MXD% r=0.75, neut# r=1.00, lymph# r=1.00, MXD# r=0.90	—
Interfering substances:	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes 	<ul style="list-style-type: none"> • WBC • RBC • MCV or Hct • Platelet • Hemoglobin • Reticulocytes
Interfering substances: differential	—	—	—
Throughput: max. CBCs per hour/Max. CBCs and differentials per hour	100/100	60/60	—
Minimum specimen volume open/Closed/Sample dead volume closed	88 µL/88 µL/1 mL	50 µL/—/—	—/15 µL/1 mL
Microsample capability	yes	yes	no
Instrument prepares microscope slides automatically/No. of automatic slide makers installed	yes/—	no/—	no/—
• Slide maker stainer sold separately or combined unit	—	—	—
Instrument archives patient data/Archiving is patient specific	yes/yes	yes/no	no/no
Maximum amount of archived data accessible when system online	30,000	40,000 samples	—
No. specimens for which numeric results saved in memory at once	30,000	40,000	100
No. specimens for which histo/cytogram results saved in memory at once	30,000	40,000	—
Instrument performs delta checks	yes	no	no
Parameters for which flags may appear	—	WBC histogram, RBC histogram, PLT histogram, error flags	WBC, RBC, PLT, HGB, HCT
Flagging is operator selectable	—	no	no
Tags and holds results for follow-up, confirmatory testing, or rerun	yes	yes	no
Parameters for flags for holding samples defined by user or vendor	—	vendor	vendor
Scattergram display: cell-specific color	yes	no	no
Histogram display: color with thresholds	yes	yes	no
User interface can display choice of specimen or result information	yes	yes	no
LIS interface formats supported	proprietary, XN series ASTM1381-95/ASTM1894-97 or XN series ASTM1381-02/ASTM1894-97	RS-232C	—
Information transferred via LIS interface	numeric and flag results, histograms and scatterplots, instrument to LIS; patient demographics, orders, LIS to instrument—broadcast; host query for demographics and orders	numeric and flag results; patient orders, LIS to instrument—broadcast; host query for patient demographics and orders	—
LOINC codes transmitted with all results/Sent in message to LIS/ Listing of machine codes and corresponding LOINC for each test	yes/yes/no	no/no/yes	no/no/no
Interface available or planned to automated specimen-handling system	no	—	no
Barcode symbologies read on specimen tube	Codabar, Code 39, Code 128, ITF, NW7, ISBT 128, JAN/EAN/UPC	Codabar, Code 39, Code 128, ITF, NW-7, UPC-A, UPC-E, JAN-8, JAN-13	proprietary system (barcodes only)
Accommodates barcode placement per CLSI standard Auto02-A2	yes	no	no
No. of cleaning or maintenance reagents required/No. of routine liquid reagents required	—	1/2	1/2 (1 diluent, 1 lyse)
Time required for daily, weekly, monthly maintenance	daily: <1 minute (operator time)	daily: <2 minutes; weekly: <2 minutes; monthly: <2 minutes	daily: 15 minutes
Onboard diagnostics for troubleshooting/Limited to software problems	yes/no	yes/no	no/no
Manufacturer can perform diagnostics via modem	yes	no	no
Distinguishing features (supplied by company)	customizable, manual gating, low maintenance, remote diagnostics, online QC, fluorescent optical platelets; discrete testing, reagent monitoring, customized chartable report formats; for use in toxicology, research, and veterinary reference labs; available in XN-1000, XN-2000, and XN-3100 configurations	automatic floating discriminators, optional upgrade to XP-300 Plus or XP-300 Linc available (data manager and small LIS); ability to directly link to EMR	CLIA-waived CBC; contains several safety measures to protect the integrity of patient results; simple operation

† 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

*XN-V Series is not FDA cleared for human use; for research use only.