

## Hematology Analyzers

	<b>Advanced Instruments</b>	<b>Alcor Scientific</b>	<b>Beckman Coulter</b>
1. What is the brand name of your company's hematology analyzer?	Norwood, Mass 800-225-4034 GloCyte@aicompanies.com www.aicompanies.com	Smithfield, RI 800-495-5270 info@alcorscientific.com alcorscientific.com	Miami, Fla 305-380-3800 mgamez@beckman.com www.beckmancoulter.com
2. What year was this version first released to market?	GloCyte automated cell counter for CSF	miniISED	DxH 690T
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	2016	2019	2019
4. What are the dimensions of the named product?	FDA 510(k) 2016	CSA CE Mark 2020	FDA 2019; CE Mark 2019
5. What is the intended use or primary function of the product?	10 inches x 6 inches x 8 inches	9.5 inches x 7.1 inches x 10.4 inches	35.5 inches x 30 inches x 31.5 inches, excluding the removable back panel
6. What types of specimen/sample does the product employ?	Provides quantitative determination of fluorescence-labeled total nucleated cells and erythrocytes in cerebrospinal fluid collected from adult and pediatric patients.	An automated sedimentation rate analyzer that reports sedimentation rate in mm/hr.	A quantitative, multiparameter, automated hematology analyzer for screening patient populations found in clinical laboratories.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Cerebrospinal fluid	100 µL whole blood (500µL dead volume)	Whole blood, predilute blood, body fluids
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Total nucleated cells (TNC) and red blood cells (RBC)	Inflammation in the blood to help diagnose certain inflammatory diseases including temporal arteritis, systemic vasculitis, and polymyalgia rheumatica.	Hematological disease, including sepsis and those developing sepsis.
9. What are the product's maximum capacity and throughput under ideal conditions?	TNC and RBC results in 5 minutes; software reports results in cells/µL	15 seconds; on screen or printout, via laboratory information system (LIS) connection	Varies upon the instrument starting state; integrated software transmits results to a laboratory information system or other. Results can also be printed.
10. Briefly describe any automation or connectivity features or options (eg, autocalibration, autodetection of specimens, onboard real-time quality control, troubleshooting) that pertain to the product.	One to two specimens in 5 minutes	180 tests per hour	Up to 100 panels per hour
11. What is the typical training time for the product?	Software interfaces with laboratory information systems; onboard quality control features include Levey-Jennings charts, password protection, and an audit table; comprehensive reports are available for printing.	LIS compatible, automixing and washing, bar code scanner	A modular system that can connect up to three units and slidemaker stainer at once to complete a workcell. Any size workcell may be connected to a laboratory automation line for full lab automation.
12. What types of technical support are available?	1 hour	30 minutes	3 days
13. What capabilities, features, or accessories distinguish this product from others on the market?	24/7 comprehensive customer service and technical support	Monday to Friday 8:30 am to 5 pm, plus remote online training.	Hotline; on-site service, application specialist, technical specialists, plus a website with learning and technical assets.
	1 cell/µL limit of detection; small 30 µL test volume; consistent turnaround time; disposable test cartridges eliminate carryover.	Faster turnaround time for SED rate ESR results. Reduced effect of temperature, hematocrit, lipema, and hemolysis.	Compact tabletop instrument benchmarking a 93% first pass yield; does not require additional aspirations or reruns for reliable results; integrated peripherals. The DxH 690T also has a unique pivotal marker, uniquely approved for detecting the high mortality disease sepsis.

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How can Bio-Rad support your mission?  
Find out more at [bio-rad.com/COVIDMolecularTesting](https://www.bio-rad.com/COVIDMolecularTesting)

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**HemoSonics**

Charlottesville, Va  
800-280-5589  
www.HemoSonics.com

DxH connected workcell	Abacus 5	Excyte Mini Automated ESR Analyzer	Quantra QPlus System: Quantra Hemostasis Analyzer, QPlus cartridge
2019 (OUS)	2013	2008	OUS 2017; US 2019 (de novo marketing authorization)
FDA 510(k) 2018; CE mark 2018.	FDA 510(k) 2012; CE mark 2010	FDA registration	CE mark 2017; FDA de novo marketing authorization for Quantra QPlus System 2019
68.5 inches x 127.39 inches x 31.2 inches, excluding optional back panel. Width varies by configuration.	16 inches x 20 inches x 18 inches	6 inches x 8 inches x 4 inches	19.25 inches x 14 inches x 12 inches
A quantitative, multiparameter, automated hematology analyzer for use in screening patient populations found in clinical laboratories.	Five-part hematology automated for measuring patients' hematology parameters within and outside of the established reference ranges.	Quantitative determination of erythrocyte sedimentation rate (ESR) of whole blood.	Evaluates the viscoelastic properties of whole blood by clot time, clot time with heparinase, clot stiffness; fibrinogen contribution to clot stiffness, platelet contribution to clot stiffness, and clot time ratio.
Bronchoalveolar lavage fluid, cerebrospinal fluid, prediluted or whole blood (venous or capillary), serous fluids, synovial fluid.	EDTA anticoagulated venous whole blood samples.	Whole blood	Whole blood
Hematological.	Enumerates CBC parameters, including 5-part WBC differentials: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HGB, HCT, MCV, MCH, MCHC, RDWcv, RDWsd, PCT, PDWcv, PDWsd, PLT, MPV, PLCC, PLCR.	Nonspecific screening test for indications of inflammation, infection, cancer, rheumatic diseases, and diseases of the blood and bone marrow.	Evaluates blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries.
Less than 2 minutes	1 minute to first result. Results available on color touchscreen display; printed to external printer; uploaded to laboratory information system	15 minutes. Results are displayed on screen, printed, or transmitted to a laboratory information system	Typically 15 minutes or less
Up to 300 samples per hour.	60 tests per hour; data storage capacity 100,000 results	10 positions, 40 samples per hour	Up to 5 single-cartridge tests per instrument per hour
Autodetection of specimens; auto rerun; onboard real-time quality control; real-time instrument monitoring for triggers, remote adjustments, troubleshooting guides, and user prompts; clot and poor sample quality detection and warning system; modular connectivity for up to three instruments and one DxH SMS II unit.	Automated calibration of measured parameters and WBC differential scatter. Connectivity to laboratory information system host via Ethernet using HL7 or RS232 serial protocol. Levey-Jennings QC files. X-B graph. Optional autoSampler and Microtainer support.	No maintenance or calibration required; closed tube sampling; autodetection of specimens; laboratory information system compatibility; onboard storage of patient samples and quality control; Youden plot graph for quick analysis of daily QC.	Automated system with fully sealed cartridge and no moving mechanical parts used as part of its sensing components. Features include robust internal quality control checks at power-on; when a new cartridge is inserted; and every 8 hours.
Can vary by region; 1 week for new users; virtual review for previous DxH users.	1 day	Less than an hour	30 minutes to 1 hour
24-hour hotline; technical applications specialist; technical products specialist; advanced support from Miami headquarters as needed.	First-line technical support by local distributors; manufacturer's technical support for training, technical advisories, software upgrades, spare parts, repairs.	Monday to Friday, 8:00 am to 6:00 pm EST	Hot-line and technical support Monday to Friday, 9:00 am to 5:00 pm EST, with emergency telephone/pager support 24/7. Additional full-service options available.
Compact instrument; requires only three reagents for a full panel CBC/differential/reticulocyte count. Early sepsis indicator objectively detects sepsis and other hematological states of interest. Automated ease-of-use capabilities; zero hands-on daily maintenance; remote instrument monitoring; self-correction; QC auto-rerun when customized.	Data station and analyzer as one unit; plug-and-play autosampler with capacity of 100 sample tubes; the same sampling probe is used by the individual sampling module and the autosampler.	Small footprint; automated system with technology based on gold standard Westergren method.	Closed cartridge system uses ultrasound to measure the shear modulus of whole blood during coagulation, allowing for accurate estimation of the relative contributions of platelets and fibrinogen to clot stiffness. Blood sample is tested without contact with moving parts or exposure to air. Dials display simplifies interpretation. Indicated for point-of-care use.



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## Instrumentation Laboratory

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## Sight Diagnostics

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Horiba Medical	Instrumentation Laboratory	Siemens Healthineers	Sight Diagnostics
ABX Micros ES 60 CS	ACL Top Family 50 Series	Advia 360 Hematology System	Olo
2014	ACL Top 750 LAS for TLA or HemoCell workcell, 2016 (US); ACL Top 750 CTS, 2016 (US); ACL Top 750, 2016 (US); ACL Top 550 CTS, 2016 (US); ACL Top 350 CTS, 2016 (US).	2015 US	2019
CE mark 2015; FDA 510(k) k141161 2014 and k170353 2017	FDA 510(k) 2015	FDA 510(k) 2015	CE Marked IVD 2018; FDA 510(k) 2019
16.9 inches x 14.2 inches x 14.2 inches	Varies by model	14.4 inches x 12.5 inches x 19.7 inches	10 inches x 11.2 inches x 12.7 inches
Identifies and enumerates the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, GRA#	Benchtop, fully automated, random access analyzers designed specifically for use in the hemostasis laboratory for coagulation or fibrinolysis testing.	Diagnosis, patient monitoring	A quantitative, multiparameter, automated hematology analyzer for use in clinical laboratories.
Whole blood	Citrated plasma	Whole blood	Whole blood
Blood cell diseases	Hemostasis based assays, including heparin-induced thrombocytopenia.	Identifies and enumerates the parameters WBC, RBC, Hb, Hct, MCV, MCH, MCHC, PLT, lymph, MID, GRA, MID%, GRA%, MPV, RDW-CV	Identifies and enumerates the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EOS%/#, BASO%/#.
65 seconds displayed, printed, transmitted to laboratory information system	Less than 3 minutes	60 seconds; results viewable on instrument monitor or through laboratory information system	Approximately 10 minutes. Results can be either displayed, printed, or transmitted to a laboratory information system (LIS) or middleware.
60 samples per hour open tube; 50 samples per hour closed tube.	Varies by model, ranging from 120 to 360 PT test results per hour.	60 complete blood count with differential per hour	Up to 5 tests per hour, including sample preparation time.
Samples are introduced through the sample tube holder. An available peer-group quality control program provides real-time QC for each analyzer.	Automates the lab's policy on sample acceptance and rejection. Provides automation to reduce required tech time. A preferred solution for total lab automation or workcell settings.	Bidirectional laboratory information system communication: integrated barcode reader for sample positive ID; integrated ticket printer.	Automatic internal fail-safe system that guarantees the consistency of the factory calibration and mitigates against user errors, consumable defects, and blood sample irregularities; advanced flagging capabilities; connectivity with LIS, middleware, and electronic patient record.
1 day	4 days	1 day	Approximately 40 minutes, provided either face-to-face or via Zoom
24/7 technical hotline support; field service support onsite Monday through Friday, 8:00 am to 5:00 pm.	Comprehensive technical support is provided 24/7.	24/7/365 technical support	Multichannel customer care (email, text, and phone) for remote and onsite support.
An integrated analyzer with ticket printer, barcode reader, virtual keyboard, and color touchscreen. Connectivity with the LiteDM patient data management system.	System provides 671 nm LED detection, minimizing interferences from hemolysis, icterus, and lipemia (HIL); on-demand heparin-induced thrombocytopenia testing; implementation and standardization of lab acceptance and rejection policies for underfilled samples, and samples with HIL levels exceeding specific assay thresholds.	Measures 16 parameters including 3-part white blood cell differential; efficient manual sampling of open and closed tubes; 60 samples per hour, volume as low as 100 µL	Requires 2 drops of blood (27 µL) from a fingerstick or a venous sample in a disposable cartridge; compact device weighs only 22 pounds and is easily adaptable to any workflow: no external reagent, no maintenance, and no liquid waste. Suitable for patients aged 3 months and above for any clinical conditions.

## Streck

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## Sysmex America

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Mini-Cube	Sysmex XN-series analyzers
2016	2012
FDA Class 1 Medical Device; FDA 510(k) exempt; CE Mark, 2016	FDA 510(k) 2012
7.5 inches x 5.3 inches x 4.9 inches	Varies by configuration
Automated instrument for determining the erythrocyte sedimentation rate of patient samples collected in K2 or K3 EDTA blood collection tubes.	Whole blood screening device for complete blood count and reticulocyte counting.
Whole blood	Whole blood
Erythrocyte sedimentation rate, used to detect the presence of inflammation in the body due to trauma, injury, or infection as well as autoimmune diseases or certain types of cancer.	Blood disorders
20 minutes in standard 13 mm x 75 mm EDTA tube; 14 minutes in BD microtainer or BD microtainer Map EDTA tube	Varies by configuration
Random access capacity of four samples; runs up to 12 samples per hour.	100 per hour per module, varies by configuration
Random access, 20-minute test results; Bluetooth printer; barcode scanner; temperature compensation factor; closed-vial collection system; walk-away capability; includes automated QC and patient data archive files.	Scalable automation configurations offer connectivity to third-party vendor total lab automation tracks, Bio-Rad Variant II Turbo Link A1c analyzer. All systems feature remote diagnostic capability, real-time quality control, and troubleshooting.
30- to 60-minute training call to optimize the system for each lab	Varies by configuration
By email or phone Monday to Friday, 8 am to 5 pm Central Time	Remote and onsite support
Compatible with standard 13 mm x 75 mm EDTA tubes as well as pediatric BD Microtainer and BD Microtainer Map EDTA tubes.	Scalable automation with flexibility to meet the needs of any laboratory.

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