

tech. guide

Hematology Analyzers

Advanced Instruments

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1. What is the brand name of your company's hematology analyzer?

GloCyte automated cell counter for CSF

miniISED

iSED

2. What is the latest version of your named analyzer; what year was this version first released to market?

2016

2019

2012

3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.

FDA 510(k); 2016.

FDA Class 1 Exempt 2019, TUV 2019, CE Mark 2020

FDA Class 1 Exempt 2012, CSA 2013, CE Mark 2012

4. What are the dimensions of the named product?

10 inches x 6 inches x 8 inches.

9.5 X 7.5 X 14

13.4 X 10.5 X 14.3

5. What is the intended use or primary function of the product?

Provides quantitative determination of fluorescence-labeled total nucleated cells and erythrocytes in cerebrospinal fluid collected from adult and pediatric patients.

An automated analyzer for the determination of erythrocyte sedimentation rate in human whole blood measured in mm/hr.

An automated analyzer for the determination of erythrocyte sedimentation rate in human whole blood measured in mm/hr.

6. What types of specimen/sample does the product employ?

Cerebrospinal fluid

100µL K2 or K3 EDTA whole blood; up to 500µL total sample volume required

100µL K2 or K3 EDTA whole blood; up to 500µL total sample volume required

7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?

Total nucleated cells (TNC) and red blood cells (RBC)

Used in evaluating, monitoring and diagnosing conditions associated with acute and chronic inflammation such as sickle cell anemia, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, chronic kidney diseases, tuberculosis, sepsis, diabetes, and cardiovascular.

Used in evaluating, monitoring and diagnosing conditions associated with acute and chronic inflammation such as sickle cell anemia, systemic lupus erythematosus, rheumatoid arthritis, inflammatory bowel disease, chronic kidney diseases, tuberculosis, sepsis, diabetes, and cardiovascular.

8. Under ideal conditions, what is the time to first result; how are the test results made available?

TNC and RBC results in 5 minutes; software reports results in cells/µL

15 seconds; results are on screen, printed and/or transmitted via LIS connection

3 minute onboard mixing/20 seconds test time; results are on screen, printed and/or transmitted via LIS connection

9. What are the product's maximum capacity and throughput under ideal conditions?

One to two specimens in 5 minutes

Single sample capacity; 180 tests per hour

20 sample capacity; 180 tests per hour

10. Briefly describe any automation or connectivity features or options that pertain to 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.

Automated washing, internal barcode scanner, LIS connectivity

Automated onboard mixing, automated washing, internal barcode scanner, internal printer, LIS connectivity

11. What is the typical training time for the product?

1 hour

<1 hour online/on demand

<1 hour online/on demand

12. What types of technical support are available?

24/7 comprehensive customer service and technical support

M-F 8:30am-5pm EST live telephone support, live callback nights/weekends/holidays

M-F 8:30am-5pm EST live telephone support, live callback nights/weekends/holidays

13. What capabilities, features, or accessories distinguish this product from others on the market?

1 cell/µL limit of detection; small 30 µL test volume; consistent turnaround time; disposable test cartridges eliminate carryover

Fast turnaround time for ESR results; high reliability maximizes uptime; small sample volume requirements; human blood based quality control with QAP; no daily maintenance; small footprint; no effects of HCT, MCV, temperature, vibrations.

Fast turnaround time for ESR results; high reliability maximizes uptime; small sample volume requirements; human blood based quality control with QAP; no daily maintenance; small footprint; no effects of HCT, MCV, temperature, vibrations.



SMALL AND MIGHTY

When time and resources are essential factors in the clinical decision-making process, the DxH 560 AL hematology analyzer can help your laboratory deliver high-quality results without compromising efficiency.

The DxH 560 AL is a multi-tube, compact analyzer with reliability and efficiency, for consistent turnaround time on results, allowing clinicians to make timely clinical decisions.

- › With high run time and less downtime for maintenance, your laboratory can count on the DxH 560 AL to be available when you need it
- › Zero hands-on daily maintenance with autonomous daily cleaning allows you to begin the day as soon as you walk in the door
- › Provide patients with timely and accurate results, with paperless data management and easy-to-access data files for up to 30,000 patient records

Propel your business with the DxH 560, the analyzer designed to meet your time, resource, and space needs.

Learn more at [beckmancoulter.com/DxH560](https://www.beckmancoulter.com/DxH560)

*Higgins, PHD, V., Tahmasebi, MSc, H., Bohn, M. K., Hall, MPH, A., & Adeli, PHD, K. (2020, June 15). CALIPER Hematology Reference Standards (II). Physician's Weekly. <https://www.physiciansweekly.com/caliper-hematology-reference-standards-ii/>.

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1. What is the brand name of your company's hematology analyzer?	DxH 500 Series	DxH 690T	DxH connected workcell
2. What is the latest version of your named analyzer; what year was this version first released to market?	DxH 560; 2020 US and OUS	2019	SW 1.2; 2019 (OUS)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE, 20215; FDA 510(K), 2018	FDA 2019; CE Mark 2019	FDA 510(k), 2018; CE mark, 2018
4. What are the dimensions of the named product?	DxH 500/520 - 17.3 inches x 10.6 inches x 16.9 DxH 560 AL - 17.3 inches x 19.7 inches x 18.1 inches	35.5 inches x 30 inches x 31.5 inches, excluding the removable back panel	68.5 inches x 127.39 inches x 31.2 inches, excluding optional back panel. Width varies by configuration.
5. What is the intended use or primary function of the product?	A quantitative, multiparameter, automated hematology analyzer for screening patient populations found in clinical laboratories.	A quantitative, multiparameter, automated hematology analyzer for screening patient populations found in clinical laboratories.	A quantitative, multiparameter, automated hematology analyzer for use in screening patient populations found in clinical laboratories.
6. What types of specimen/sample does the product employ?	Whole blood, predilute blood	Whole blood, predilute blood, body fluids.	Bronchoalveolar lavage fluid, cerebrospinal fluid, prediluted or whole blood (venous or capillary), serous fluids, synovial fluid.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Hematological	Hematological disease, including sepsis and those developing sepsis	Hematological
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to first result is 60 seconds or less. Integrated software transmits results to a laboratory information system or other. Results can also be printed.	Varies upon the instrument starting state; integrated software transmits results to a laboratory information system or other. Results can also be printed.	Less than 2 minutes
9. What are the product's maximum capacity and throughput under ideal conditions?	DxH 560 AL - load up to 50 samples without the need to stop analysis. DxH 500/520 - One sample Testing up to 60 samples/hour	Up to 100 panels per hour	Up to 300 samples per hour
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Automated calibration, sample auto-detection (DxH 560 AL), automated sample rerun, automated QC rerun, Automated ease-of-use capabilities; zero hands-on daily maintenance	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.	Autodetection of specimens; auto rerun; onboard real-time quality control; modular connectivity for up to 3 instruments and one DxH SMS II unit.
11. What is the typical training time for the product?	Half a day or less	3 days	Can vary by region; 1 week for new users; virtual review for previous DxH users.
12. What types of technical support are available?	Hotline; on-site service, application specialist, technical specialists, plus a website with learning and technical assets.	Hotline; on-site service, application specialist, technical specialists, plus a website with learning and technical assets.	24 hour hotline; technical applications specialist; technical products specialist; advanced support from Miami headquarters as needed.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Compact instrument; requires only three reagents for a full CBC with differential. Automated ease-of-use capabilities; Robust QC package.	Compact tabletop instrument benchmarking a 93% first pass yield; does not require additional aspirations or reruns for reliable results; integrated peripherals.	Compact instrument; requires only 3 reagents for a full panel CBC/differential/reticulocyte count. Early sepsis indicator objectively detects sepsis and other hematological states of interest.

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Diatron

Budapest, Hungary
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www.diatron.com

EliTechGroup

Puteaux, France; Logan, Utah
www.elitechgroup.com

HemoSonics

Charlottesville, Va
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www.HemoSonics.com

CellaVision DM and DC series analyzers	Abacus 5	Excyte Mini Automated ESR Analyzer	Quantra QPlus System: Quantra Hemostasis Analyzer, QPlus cartridge
CellaVision DC-1 - 2020	2013	2008	OUS 2017; US 2019 (de novo marketing authorization)
CE Mark 2019; FDA 510(k) 2020	FDA 510k 2012; CE mark 2010	FDA registration	CE mark 2017; FDA de novo marketing authorization for Quantra QPlus System 2019
14.6 inches x 11.0 inches x 15.4 inches	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
Differential count of white bloodcells (WBC), characterization of red blood cell (RBC) morphology and platelet estimation.	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.
Peripheral whole blood samples typically flagged by a cell-counter indicating an abnormal morphology	EDTA anticoagulated venous whole blood samples	Whole blood	Whole blood
Automated cell-locating device for cell-location and identification of RBC, WBC or platelets for in-vitro use. Verification of results by human operator	Enumerates CBC parameters, including 5-part WBC differentials	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 hypo-coagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries.
Approximately 2- 6 minutes per slide depending on analyzer	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.
10 -30 slides/h for complete differential (100 WBC+RBC+PLT) depending on analyzer	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.
Leverages high-speed robotics and digital imaging to automatically locate and capture high-quality images of cells. Review of blood smears can be local or remote by morphology experts at other sites	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; auto-detection of specimens; LIS compatibility; onboard storage of patient samples and QC; Yudson 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.
1 day	1 day	Less than an hour	30 minutes to 1 hour
First line support by local distribution partners	First-line technical support by local distributors; manufacturer's technical support for training, technical advisors, 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.
Automates and simplifies the process of performing blood cell differentials in low-volume laboratories and improves collaboration with colleagues and morphology experts at other sites	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.

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1. What is the brand name of your company's hematology analyzer?	ABX Micros ES60	ABX Pentra 60C+	ABX Pentra XL80
2. What is the latest version of your named analyzer; what year was this version first released to market?	ABX Micros ES 60 USA 2014	ABX Pentra 60C+, USA 2000	ABX Pentra XL80, USA 2003
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE Mark, 2015 FDA 510(k), 2014	CE Mark, 2010 FDA 501(k), 2000	CE Mark, 2012 FDA 510(k), 2003
4. What are the dimensions of the named product ?	16.9 x 14.2 x 14.2	20.3 x 17.5 x 19	21.5 x 32.3 x 22.4
5. What is the intended use or primary function of the product?	Intended use: The ABX Micros ES 60 analyzer is a quatitative 3-part Diff automated hematology system used for in-vitro diagnostic testing of whole blood specimens in clinical laboratories.	Fully automated 5-part diff hematology system used for the in-vitro diagnostic testing of whole blood specimens in clinical laboratories.	Fully automated 5-part Diff hematology system with an autoloader used for the in-vitro diagnostic testing of whole blood specimens in clinical laboratories.
6. What types of specimen/sample does the product employ?	Whole blood	Whole blood	Whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Blood cell diseases	Blood cell diseases	Blood cell diseases
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to results 65 seconds displayed, printed and or transmitted to LIS or EMR	60 seconds displayed, printed, transmitted to LIS or EMR	Time to results 45 seconds displayed, printed and or transmitted to LIS or EMR
9. What are the product's maximum capacity and throughput under ideal conditions?	Max throughput: Open tube 60 samples per hour. Closed tube 50 samples per hour	up to 60 samples/hour	80 samples/hour; random continuous access of the autoloader
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Samples are introduced thru the Sample Tube holder. QC-RT is a Peer Group QC Program that is available to HORIBA customers and provides real-time QC for each analyzer.	Samples are introduced thru the Sample Tube holder. QC-RT is a Peer Group QC Program that is available to HORIBA customers and provides real-time QC for each analyzer.	Has an autoloader that can handle 10 racks of 10 tubes each at one time. You can continue to add sample racks. You can interrupt the Sample run and introduce a stat sample in the STAT sample tube holder.
11. What is the typical training time for the product?	1 day	1.5 days	2 days
12. What types of technical support are available?	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00am - 5:00pm	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00am - 5:00pm	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00am - 5:00pm
13. What capabilities, features, or accessories distinguish this product from others on the market?	An integrated analyzer with printer, barcode reader and vitural key-board with a Color Touch screen Connectivity with the LiteDM Patient Data Management System. "A Completely interfaced lab on one Bench"	MDSS. Precision pipetting, No shear valve, no maintenance, reduces sample volume, Reduces clogging. DHSS. Ensures accurate cell by cell counting, Flow cell with focused flow impedance, cytochemical staining and optical light scatter.	MDSS Precision pipetting, no shear valve, no maintenance, reduces sample volume, reduces clogging. DHSS Ensures accurate cell by cell counting, Flow cell with focused flow impedance, cytochemical staining and optical light scatter.

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Lite (DM) Patient Data Management System	BC-3600	BC-5390	HemoScreen
Lite (DM) USA 2013 FDA Class 1 Product Code OUG Medical Device Data System exempt from listing and registration	FDA 510K 2015	FDA 510K 2016	2018
Class 1 Medical device for data	FDA 510K, Health Canada	FDA 510K, Health Canada	CE-Mark, 2013; FDA 510(k), 2018; TGA, 2020
9 x 10 x 10	18" x 16" x 18"	21" x 22" x 23"	10.2 x 6.9 x 11.8
Acts as middleware allowing the lab to connect their chemistry, hematology, immunoassay and urinalysis analyzers to the LiteDM.	Blood disorder screening	Blood disorder screening	Point-of-care CBC testing
Handles test results for any sample	Whole blood EDTA	Whole blood EDTA	One drop of capillary or venous blood
N/A	Blood cells disorders	Blood cells disorders	HemoScreen analyzes 20 standard blood count parameters, delivering full and accurate CBC results
With LiteDM within 1 minutes of processing samples	1 minute per CBC with Differential with histograms	1 minutes per CBC with differential with histogram and a scattergram	The test takes 5 minutes and can be performed by virtually anyone. Test results are displayed on the interactive, user-friendly screen.
Storage is at least 100,000 sample results from a variety of medical devices stored under each patient's medical record and transmitted to either EMR or LIS	Max capacity: 1 tube per run, Throughput: 60 samples/hour throughput	Max capacity: 40 tubes autoloader, Throughput: 60 samplese per hour.	11 x 5-part differential CBC per hour or 20 x 3-part diff
The majority of chemistry, hematology, immunoassay and urinalysis analyzers can connect to the LiteDM. EMR and LIS connections are available.	The barcode reader and LIS connectivity enable seamless sample data transmission. Auto-Startup and standby functions. Nearly all scheduled maintenance procedures are automated by touch buttons.	Built-in Data Management Software enhances patient result storage and sorting. Auto-sampling via auto-loader. .	HemoScreen is autocalibrated due to lab-on-a-cartridge technology, and enables autodetection of specimens by proprietary machine vision algorithms. .
1 day	Half a day	Up to one day	1 hour
24/7 Technical Hotline support, Field Service support on-site M-F 8-5	Hotline, phone call, on-site as necessary	Hotline, phone call, on-site as necessary	Online training, remote diagnostics and remote intervention, remote application support and local technical support
Ability to connect up to four different analyzers. All of the HORIBA Medical analyzers can be connected and the following 3rd party medical devices: Abaxis Piccolo Xpress, Tosoh AIA 360, Quidel Triage, Siemens Clinitek Status, Mckesson 120 and other urine strip readers.	16 parameters + 3 histograms; closed tube sampling; cyanide free reagents; built-in diluent dispenser for predilution mode, all-in-one CBC result screen display; results at a glance; only one maintenance reagent; storage capacity of 40,000 results with histograms; uploadable QC files via USB driver; ensure accuracy and convenient.	21 parameters/3 histograms/1 scattergram; 40-tube autoloader; 33ul sample for CBCD; STAT sampling; sample tube adaptors for pediatric samples; built-in diluent dispenser for pre-dilution mode; remarkable 36 hours refrigeration sample stability; only one maintenance reagent; 60 uploadable QC files via USB drive.	Imaging flow cytometry: a novel technology combining ul sample volumes, high speed microscopic imaging and morphological classification by AI. Single use cartridges contain all reagents and the sample. The analyzer is maintenance free, and portable without need for calibration. It is the fastest, dry, full CBC analyzer.

Hematology Analyzers

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1. What is the brand name of your company's hematology analyzer?	Advia 360 Hematology System	Advia 560 Hematology System	Advia 2120i
2. What is the latest version of your named analyzer; what year was this version first released to market?	2015 US	2015 US	2008 US
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k) 2011	FDA 510(k) 2011	FDA 510(k) 2017 latest RoHS compliant
4. What are the dimensions of the named product?	14.4 in x 12.5 in x 19.7 in	52 (h) x 41 (w) x 49 (d) cm; 20 (h) x 16 (w) x 19 (d) in	33.8 in x 31.9 in x 26.8 in without autosampler; 33.8 in x 55.5 in x 26.8 in with autosampler
5. What is the intended use or primary function of the product?	Diagnosis, patient monitoring	Diagnosis, patient monitoring	Diagnosis, patient monitoring
6. What types of specimen/sample does the product employ?	Whole blood	Whole blood	Cerebrospinal, pericardial, peritoneal, or pleural fluids; whole blood.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Identifies and enumerates the following parameters, including 3-part WBC-differential: WBC, LYM, MID, GRA, LYM%, MID%, GRA%, RBC, MCV, HCT, HGB, MCH, MCHC, PLT, MPV	Identifies and enumerates the following parameters, including 5-part differential with two histograms and scattergrams for RBC and PLT: BASO, WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, RBC, HCT, MCV	Complete blood count parameters Baso, CHCM, CHCMr, CHr, Eos, Hb, Hct, HDW, LUC%, Lymph, MCH, MCHC, MCV, MCVr, Monos, MPV, Neu %, PLT, RBC, RDW, retic %, and WBC; cerebrospinal fluid parameters cellular Hgb, Lymph, MN, Monos, Neu, PMN, RBC, and WBC
8. Under ideal conditions, what is the time to first result; how are the test results made available?	60 seconds; results viewable on instrument monitor or through laboratory information system	60 seconds; results viewable on instrument monitor or through laboratory information system	30 seconds; results viewable on instrument monitor or through laboratory information system.
9. What are the product's maximum capacity and throughput under ideal conditions?	60 complete blood count with differential per hour	60 complete blood count with differential per hour	120 complete blood count with differential per hour
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Bidirectional laboratory information system communication: integrated barcode reader for sample positive ID; integrated ticket printer.	Bidirectional laboratory information system communication: integrated barcode reader for sample positive ID; integrated ticket printer. Optional external windows compatible printer.	Connection available to Aptio lab automation; automated daily maintenance; onboard specimen detection; onboard troubleshooting guides.
11. What is the typical training time for the product?	1 day	1 day	1 week operator training
12. What types of technical support are available?	24/7/365 technical support	24/7/365 technical support	24/7/365 technical support
13. What capabilities, features, or accessories distinguish this product from others on the market?	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	60 samples per hour, volume as low as 110µL; Laser light scatter technology for 5-part WBC differential; impedance method for CBC: WBC (80), RBC, and PLT (70); light absorbance for HGB measurement/20 parameters; aids in interpreting disease state information with 2 scattergrams and 2 histograms per result.	Detection of cellular Hgb, CHCM, and CHr is unique to Advia; multispecies software for research and veterinary applications.

Sight Diagnostics

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1. What is the brand name of your company's hematology analyzer?	Sight OLO	MINI-CUBE	Sysmex XN-series analyzers
2. What is the latest version of your named analyzer; what year was this version first released to market?	2019	2016	2012
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k) 2019; CE Marked 2018	FDA Class 1 Medical Device; FDA 510(k) exempt; CE Mark, 2016	FDA 510(k) 2012
4. What are the dimensions of the named product?	10 inches x 11.2 inches x 12.7 inches	7.5 inches x 5.3 inches x 4.9 inches	Varies by configuration
5. What is the intended use or primary function of the product?	A quantitative, multiparameter, automated hematology analyzer designed to provide CBC information in near-patient, moderately complex laboratories.	Automated instrument for determining the erythrocyte sedimentation rate of patient samples collected in K ₂ or K ₃ EDTA blood collection tubes.	Whole blood screening device for complete blood count and reticulocyte counting.
6. What types of specimen/sample does the product employ?	Whole blood	Whole blood	Whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Identifies and enumerates 5-part differential 19 parameter CBC results, including WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EOS%/#, BASO%/#	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
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Approximately 10 minutes. Results can be either displayed, printed, or transmitted to a laboratory information system (LIS) or middleware	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
9. What are the product's maximum capacity and throughput under ideal conditions?	Up to 5 tests per hour, including sample preparation time	Random access capacity of 4 samples; runs up to 12 samples per hour	100 per hour per module, varies by configuration
10. Briefly describe any automation or connectivity features or options that pertain to the product.	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.	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.
11. What is the typical training time for the product?	Approximately 30 minutes, provided either face-to-face or via conference call	a 30- to 60- minute training call to optimize the system for each lab	Varies by configuration
12. What types of technical support are available?	Multichannel customer care (email, text, and phone) for remote and onsite support. 24/7 customer service line available.	By email or phone Monday to Friday, 8 am to 5 pm Central Time	Remote and onsite support
13. What capabilities, features, or accessories distinguish this product from others on the market?	Requires only 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 or wet reagents, no maintenance, and no liquid waste. Suitable for patients aged 3 months and above for any clinical conditions	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.