tech guide

Hematology & Coag Analyzers

	Beckman Coulter	CellaVision	Diagnostica Stago Inc.
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1. What is the brand name of your company's hematology and/or coag analyzer?	DxH500 Series	CellaVision DM and DC series analyzers	STA R Max
2. What is the latest version of your named analyzer; what year was this version first released to market?	DXH560 AL, 2020 US and 2021 OUS	CellaVision DC-1 - 2020	2015
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE Mark 2021; FDA 510(k) - 2018	CE Mark 2019; FDA 510(k) 2020	FDA 510(k)
4. What are the dimensions of the named product?	DxH 500/520 - 17.3"x10.6"x16.9" DxH 560 - 17.3"x10.6"x19.7"	14.6" x 11.0" x 15.4"	49.2"x50.3"x32.2"
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.	Differential count of white bloodcells (WBC), characterization of red blood cell (RBC) morphology, and platelet estimation.	Fully automatic high-throughput hemostasis analyzer designed to perform coagulation tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.
6. What types of specimen/sample does the product employ?	Whole blood, predilute blood	Peripheral whole blood samples typically flagged by a cell-counter indicating an abnormal morphology	Spun plasma
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Hematological disease	Automated cell-locating device for cell location and identification of RBC, WBC, or platelets for in-vitro use. Verification of results by human operator	Blood clotting disorders and anticoagulation monitoring
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Less than 1 minute. Integrated software transmits results to a laboratory information system, or other results can also be printed	Approximately 2- 6 minutes per slide depending on analyzer	Varies based on testing configuration. <6 minutes; results appear on workstation screen, transmitted to LIS.
9. What are the product's maximum capacity and throughput under ideal conditions?	DxH 560 - 50 samples/hour DxH 500/520 - 60 samples/hour	10 -30 slides/h for complete differential (100 WBC+RBC+PLT) depending on analyzer	215 samples onboard, 70 reagents onboard
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 reminders and rerun, automated ease-of-use capabilities; zero hands-on daily maintenance	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	Precalibrated reagents, integrated bar code reader, full auto-verification, repeat/reflex testing, comprehensive QC, accreditation tools, maintenance logs, TAT monitoring and maintains 5 years of patient archives onboard, auto-upload of QC to peer group system, remote access support.
11. What is the typical training time for the product?	Varies by region; up to 2 Days	1 day	Company offers 3 day training at the US HQ
12. What types of technical support are available?	Hotline; on-site service, application specialist, technical specialists, plus a website with learning and technical assets	First line support by local distribution partners	Field-based technical support and field support groups
13. What capabilities, features, or accessories distinguish this product from others on the market?	Compact instrument that requires only 3 reagents for a full CBC with differential. Automated ease-of-use capabilities and robust QC package.	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.	Viscosity-based mechanical clot detection, chromogenic, and immunoturbidometric testing; pre-calibrated D-Dimer and fibrinogen; full complement of lupus anti-coagulant testing; STA Coag Expert data management system and Connect. One e-solutions deliver full auto-verification, repeat/reflux testing, auto upload of QC to peer group and remote access support.

DiaPharma Group Inc.	**ELITechGroup**	**ELITechGroup**	**HemoSonics**
West Chester, OH 800-526-5224 info@diapharma.com www.diapharma.com	Logan, UT 435-752-6011 getexcyted.com	Logan, UT 435-752-6011 getexcyted.com	Durham, NC 800-280-5589 www.hemosonics.com
T-TAS 01	Excyte Mini Automated ESR Analyzer	Excyte 20 Automated ESR Analyzer	Quantra Hemostatis System
US 2020	2008	2006	OUS 2017, US 2019
FDA 510(K), 2020; CE Mark, 2018; PMDA, 2021	FDA Class 1 Exempt 2008	FDA Class 1 Exempt 2006	CE Mark, 2017 FDA De Novo 2019 QPlus Cartridge FDA 510(k), 2022 QStat Cartridge
320(W)x247(H)x360(D) mm	6" x 8" x 4"	8.5" x 13.5" x 10.5"	19.25" x 14" x 12"
Assessment of total platelet function in clinical laboratories. One test, one Result.	Quantitative determination of erythrocyte sedimentation rate (ESR) in whole blood.	Quantitative determination of erythrocyte sedimentation rate (ESR) in 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, clot stability to lysis, and clot time ratio.
315 uL Whole Blood	Whole blood	Whole blood	Whole blood
Primary hemostasis dysfunction and known anti-platelet medication.	Nonspecific screening for indications of inflammation, infection, cancer, rheumatic diseases, and diseases of the blood and bone marrow	Nonspecific screening for indications of inflammation, infection, cancer, rheumatic diseases, and diseases of the blood and bone marrow	Evaluates coagulation in perioperative patients to assess hypocoagulable and hypercoagulable conditions in cardiovascular, trauma, liver transplantation, and major orthopedic surgeries.
10-minute runtime, results displayed to software	15 minutes. Results are displayed on screen, printed, or transmitted to a laboratory information system (LIS)	15 minutes. Results are displayed on screen, printed, or transmitted to a laboratory information system (LIS)	Typically 5 minutes for first results, and complete results in under 15 minutes. Printed and or transmitted to LIS or EMR.
Up to 12 samples per hour	10 positions, 40 samples per hour	20 positions, 80 tests per hour	Up to 5 single-cartridge tests per instrument per hour.
Automated chip detection/ identification. Optional barcode reader for positive sample ID. 2 levels of automated QC	No maintenance or calibration is required; closed tube sampling; auto-detection of specimens; LIS compatibility; onboard storage of patient samples and QC; Yudon plot graph for quick analysis of daily QC	No maintenance or calibration is required; closed tube sampling; auto-detection of specimens; LIS compatibility; onboard storage of patient samples and QC; Yudon plot graph for quick analysis of daily QC	Automated ultrasound system with fully sealed cartridge. No moving mechanical parts used as part of sensory components. Robust internal quality control checks conducted at power-on, when a new cartridge is inserted, and every 8 hours.
Half day	Less than an hour	1 to 2 hours	30 minutes to 1 hour
M-F 8-8 Eastern Time. On site as necessary.	Monday to Friday, 8:00 am to 6:00 pm Eastern Time	Monday to Friday, 8:00 am to 6:00 pm Eastern Time	Hotline 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.
Physiologic flow conditions to mimic the in vivo environment. A single test for a global picture of primary hemostasis.	Small footprint; automated ESR testing based on gold standard Westergren method.	Small footprint; onboard mixer, scanner, and printer; automated ESR testing based on gold standard Westergren method.	Closed cartridge system uses ultrasound to measure the shear modulus of whole blood during coagulation, allowing for fast, accurate estimation of the relative contributions of platelets, factors, and fibrinogen to clot stiffness. Easy to interpret dials display allows users to interpret results quickly and with confidence.

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ABX Micros ES60	ABX Pentra 60C+	ABX Pentra XL80	NEO Iris
ABX Micros ES 60, USA 2014	ABX Pentra 60C+, USA 2000	ABX Pentra XL80, USA 2003	6/12/20
CE Mark, 2015 FDA 510(k), 2014	CE Mark, 2010 FDA 501(k), 2000	CE Mark, 2012 FDA 510(k), 2003	FDA 510(k)
16.9" x 14.2" x 14.2"	20.3" x 17.5" x 19"	21.5" x 32.3" x 22.4"	73.2" H x 86.6" W x 35.4" D
Intended use: The ABX Micros ES 60 analyzer is a quantitative 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.	The NEO Iris is designed to automate standard immunohematology assays using a microplate-based platform.
Whole blood	Whole blood	Whole blood	Whole blood and plasma
Blood cell diseases	Blood cell diseases	Blood cell diseases	ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping, and antigen screening
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	ABORH & Pool Cell Screen is 32 min.; antibody Id is 30 min.; weak D is 27.5 min.; IgG Crossmatch is 37.4 min.; DAT is 18 min.; CMV is 23.1 min.
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	Up to 224 samples; multiple linear racks of 16 samples each; continuous load and unload via LED user interface
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.	Dynamic workflow and resource handling; bi-directional interface; Serial RS232 or LAN; enhanced data management with ImmuLINK; automated washer with aspirate and dispense verification; plate centrifuge & plate shaker for full or partial microplates
1 day	1.5 days	2 days	
24/7 technical hotline support; field service support onsite Monday through Friday, 8:00am to 5:00pm	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00am to 5:00pm	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00am to 5:00pm	Technical support available 24/7 and highly secure and compliant remote support through Blud_Direct.
An integrated analyzer with printer, barcode reader and vitural keyboard 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.	Is Immucor's most productive, fully-automated blood bank instrument. It provides efficiencies with high type and screen throughput. With linear sample and reagent racks for true continuous access, STAT capabilities and dynamic workflow management tool to run any test, in any order, at any time.

FAST. EASY. RELIABLE.

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Acusera Hematology Control	Scopio X100	Advia 560 Hematology System	Advia 360 Hematology System
	Scopio X100 - 2021	2015 US	2015 US
CE Mark FDA 510(k) clearance Health Canada Licence	CE mark, 2020 FDA 510(k), 2020	FDA 510(k) 2011	FDA 510(k) 2011
	Scanner (HxWxD): 15"x12.8"x14.2" Processing unit (HxWxD): 12.6"x6.8"x14.2"	20" (h) x 16" (w) x 19" (d)	14.4" x 12.5" x 19.7"
Intended as an internal quality control for hematology analysis	Locate and display images of white cells, red cells, and platelets acquired from peripheral blood smears to conduct a WBC differential, RBC morphology evaluation, and platelet estimation.	Diagnosis, patient monitoring	Diagnosis, patient monitoring
100% Human Whole Blood	Whole blood	Whole blood	Whole blood
BASO*, % BASO, BASO-X, BASO –Y, DIFF-X, DIFF-Y, EOS, %EOS, FSC-X, HCT, HGB, HPC, IMIDC, IMIRF, IG, %IG, IMI, IPF, LYMPH, % LYMPH, MCV, MCH, MCHC, MPV, MONO, % MONO, NEUT, % NEUT, NRBC-X, NRBC-Y, NRBC*, %NRBC, PDW, P-LCR, PCT, PLT, PLT-0, RBC, RBC-X, RBC-Y, RDW-CV, RDW-SD, RBC-O, WBC, WBC-D *This product may not be suitable for the control of NRBC# and Basophils on some Sysmex models	Hematological	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	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
Same as patient sample	Time between triggering a scan and viewing results in the Full-Field PBS application is approximately 3-7 minutes, depending on selected scan mode.	60 seconds; results viewable on instrument monitor or through laboratory information system	60 seconds; results viewable on instrument monitor or through laboratory information system
	15 slides/h for complete differential (200 WBC+RBC+PLT)	60 complete blood count with differential per hour	60 complete blood count with differential per hour
Connects to Acusera 24.7, our interlaboratory data management software. With the unique ability to generate real time peer group data while also automatically calculating measurement uncertainty.	A full-field digital image created at 100X resolution with automated end-to-end sample analysis. Built-in barcode reader. Secure browser-based remote connectivity from any location. Seamless LIS integration. Self-service automated troubleshooting.	Bidirectional laboratory information system communication: integrated barcode reader for sample positive ID; integrated ticket printer. Optional external Windows compatible printer.	Bidirectional laboratory information system communication: integrated barcode reader for sample positive ID; integrated ticket printer.
This control is liquid ready to use. Therefore minimal preparation and training time required	3 hours	1 day	1 day
24/7 phone and email support, online educational material and references, onsite support (available in certain circumstances)	Self-service troubleshooting triggered automatically by the device: 24/7 off-site technical support; application specialist; local technical support onsite as necessary	24/7/365 technical support	24/7/365 technical support
Combining 45 analytes in total the Randox Acusera Hematology quality control completely covers the commonly tested full blood profile in a single control. Providing a true third-party solution for Sysmex and Mindray hematology analyzers with 5-part differential technology an unbiased, independent assessment of analytical performance is guaranteed.	Includes full-field image of all clinical areas of interest including feathered edge, adaptive monolatyer identification, WBC detection and pre-classification into 14 classes, RBC morphology evaluation from 1,000 FOVs, PLT pre-estimation from 10 FOVs, real-time review and collaboration from anywhere.	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.	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

Sysmex America Lincolnshire, IL communications@sysmex.com	**Werfen** Bedford, MA 1-800-955-9525 customerservice.na@werfen.com werfen.com
Sysmex XN-Series	Werfen
2012	ACL TOP Family 50 Series Hemostasis Testing Systems, 2015
FDA 510(k) 2012	FDA 510K (2015)
Varies by configuration	29" x 32" x 33"—ACL TOP 350 29" x 43" x 35"—ACL TOP 550 29" x 60" x 35"—ACL TOP 750
Whole blood screening device for complete blood count and reticulocyte count.	Diagnosis, patient monitoring, therapeutic drug monitoring.
Whole blood	Plasma
WBC, RBC, Hgb, HCT, MCV, MCH, MCHC, PLT, Neut %#, Lymph %#, Mono %#, Baso %#, EOS %#, NRBC %&#, IG %&#, MPV, PLT-F, IPF, RDW-CV, RDW-SD, retic %&#, IRF, RET-He; body fluids: RBC-BF, TC-BF, WBC-BF, MN %&#, PMN %&#	Hemophilia, Von Willebrand disease, clotting factor deficiencies, hypercoagulate states, deep venous thrombosis.
<1 minute instrument display, instrument printout, electronic interface with laboratory information system."	<3 min results appear on screen, transmitted to laboratory information system.
Each XN module: 100 specimens/hour	ACL TOP 350—110 tests per hour ACL TOP 550—240 tests per hour ACL TOP 750—360 tests per hour
Scalable automation configurations offer connectivity to third-party vendor total lab automation tracks. All systems feature remote diagnostic capability, real-time quality control, and troubleshooting.	Specialized automation workcell that intergrates all phases of hemostasis testing for optimal testing. All ACL TOP Family 50 Series systems are fully automated, equipped with liquid level sensing, intergrated barcode for true sample detection.
Varies by configuration	1 week operator training.
Remote and on-site support	24/7 comprehensive customer service and technical support
Integration of the DI-60 automated cell image system, providing preclassification for WBC, RBC, and PLT estimates; tube sorter/archiver (TS-10) and integration of A1c testing provide complete testing efficiencies; optional configuration (XN-20) possesses the white cell precursor channel (WPC), which differentiates a single flag into 2 distinct flags.	ACL TOP Family 50 Series System offers unique features: tube fill height check, aspiration preassure check, test feasibility feature, detection of interfering substances, intergrated barcode reader, HemoHub intelligent data manager.