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Hematology & Coag Analyzers

	Advanced Instruments	bioMérieux, Inc.	CellaVision
	Norwood, MA 800-225-4034 GloCyte@aicompanies.com www.aicompanies.com	Salt Lake City, Utah 800-682-2666 www.biomerieux-usa.com	Lund, Sweden 0046 46 460 16 00 www.cellavision.com
1. What is the brand name of your company's hematology and/or coag analyzer?	GloCyte automated cell counter for CSF	VIDAS 3	CellaVision DM and DC series analyzers
2. What is the latest version of your named analyzer; what year was this version first released to market?	2016	2015	CellaVision DC-1 - 2020
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k); 2016.	TUV CE Mark, 2013; FDA 510(k), 2015	CE Mark 2019; FDA 510(k) 2020
4. What are the dimensions of the named product?	10" x 6" x 8".	24" x 29.5" x 25.5"	14.6" x 11.0" x 15.4"
5. What is the intended use or primary function of the product ?	Provides quantitiative determination of fluorescence-labeled total nucleated cells and erythrocytes in cerebrospinal fluid collected from adult and pediatric patients.	Diagnosis and patient monitoring	Differential count of white bloodcells (WBC), characterization of red blood cell (RBC) morphology, and platelet estimation.
6. What types of specimen/ sample does the product employ?	Cerebrospinal fluid	Serum, plasma, stool	Peripheral whole blood samples typically flagged by a cell-counter indicating an abnormal morphology
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Total nucleated cells (TNC) and red blood cells (RBC)	Thrombosis (D-DIMER exclusion), sepsis (procalcitonin), infectious diseases (SARS-CoV-2, measles, mumps, rubella, varicella, Lyme, *C. difficile*, *H. pylori*, toxoplasma, CMV), and pregnancy (HCG)	Automated cell-locating device for cell-location and identification of RBC, WBC or platelets for in-vitro use. Verification of results by human operator
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	20 minutes (assay dependent); test results automatically sent to LIS (laboratory information system) and available onscreen or printed	Approximately 2- 6 minutes per slide depending on analyzer
9. What are the product's maximum capacity and throughput under ideal conditions?	One to two specimens in 5 minutes	Processes up to 36 tests per hour (12 assays onboard simultaneously); stat processing available	10 -30 slides/h for complete differential (100 WBC+RBC+PLT) depending on analyzer
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 pipetting and calibration, onboard dilution, bi-directional connectivity with LIS, sample stability management, integrated quality control, barcode traceability, walkaway processing	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
11. What is the typical training time for the product?	1 hour	1.5 day training on-site at customer location	1 day
12. What types of technical support are available?	24/7 comprehensive customer service and technical support	Remote monitoring; remote support services available 24/7/365 via screen-sharing for immediate solutions; skilled specialists for on-site instrument maintenance	First line support by local distribution partners
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	Reliable, easy-to-use benchtop immunoassay system with a mean time between failure of more than a year; features routine and emergency (stat) testing in a ready-to-use assay format adaptable to batch or single test runs; offers specialty menu of critical care and infectious disease assays.	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.

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Hematology

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ABX Micros ES 60

Hematology

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Yumizen H2500

Hemostasis

HORIBA Medical provides a new comprehensive range of hemostasis reagents and systems, the Yumizen G** range offered worldwide

Yumizen G800

Pentra 400

HORIBA Medical

Clinical Chemistry

HORIBA Medical provides a comprehensive moderate complexity drugs-of-abuse and general chemistry menu

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- Increase Revenue

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HORIBA Medical provides Big Lab Automation in a Small Footprint™ with its next generation chemistry system

Yumizen C1200

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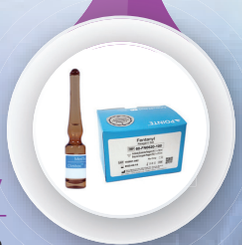

Toxicology

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	DiaPharma Group, Inc. West Chester, Ohio 800-526-5224; info@diapharma.com www.diapharma.com	ELITechGroup Logan, Utah 435-752-6011 elitechgroup.com	ELITechGroup Logan, Utah (435) 752-6011 elitechgroup.com
1. What is the brand name of your company's hematology and/or coag analyzer?	T-TAS 01	Excyte Mini Automated ESR Analyzer	Excyte 20 Automated ESR Analyzer
2. What is the latest version of your named analyzer; what year was this version first released to market?	US 2020	2008	2006
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(K), 2020; CE Mark, 2018; PMDA, 2021	FDA Class 1 Exempt 2008	FDA Class 1 Exempt 2006
4. What are the dimensions of the named product?	320(W)x247(H)x360(D) mm	6" x 8" x 4"	8.5" x 13.5" x 10.5"
5. What is the intended use or primary function of the product ?	A quantitative, semi-automated analyzer for the assessment of total platelet funtion in clinical laboratories.	Quantitative determination of erythrocyte sedimentation rate (ESR) in whole blood	Quantitative determination of erythrocyte sedimentation rate (ESR) in whole blood
6. What types of specimen/sample does the product employ?	315 µL BAPA anticoagulated whole blood	Whole blood	Whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	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
8. Under ideal conditions, what is the time to first result; how are the test results made available?	10 minute runtime, results displayed to software	15 minutes. Results are displayed on screen, printed, or transmitted to an laboratory information system (LIS)	15 minutes. Results are displayed on screen, printed, or transmitted to an laboratory information system (LIS)
9. What are the product's maximum capacity and throughput under ideal conditions?	Up to 12 samples per Hour	10 positions, 40 samples per hour	20 positions, 80 tests per hour
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.	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; autodetection 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; autodetection of specimens; LIS compatibility; onboard storage of patient samples and QC; Yudon plot graph for quick analysis of daily QC
11. What is the typical training time for the product?	Half day	Less than an hour	1 to 2 hours
12. What types of technical support are available?	Phone call and email technical support. On-site as necessary.	Monday to Friday, 8:00 am to 6:00 pm EST	Monday to Friday, 8:00 am to 6:00 pm EST
13. What capabilities, features, or accessories distinguish this product from others on the market?	Physiologic flow conditions with no exogenous agonist more closely mimics in vivo conditions. A single test with easy to intrepret results provides a better clinical 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.

HemoSonics Charlottesville, VA 800-280-5589 www.HemoSonics.com	**HORIBA Medical** U.S. Headquarters: Irvine, CA 888-903-5001 www.horiba.com	**HORIBA Medical** U.S. Headquarters: Irvine, CA 888-903-5001 www.horiba.com	**HORIBA Medical** U.S. Headquarters: Irvine, CA 888-903-5001 www.horiba.com
Quantra QPlus System: Quantra Hemostasis Analyzer, QPlus cartridge	ABX Micros ES60	ABX Pentra 60C+	ABX Pentra XL80
OUS 2017; US 2019 (de novo marketing authorization)	ABX Micros ES 60 USA 2014	ABX Pentra 60C+, USA 2000	ABX Pentra XL80, USA 2003
CE mark 2017; FDA de novo marketing authorization for Quantra QPlus System 2019	CE Mark, 2015 FDA 510(k), 2014	CE Mark, 2010 FDA 501(k), 2000	CE Mark, 2012 FDA 510(k), 2003
19.25" x 14" x 12"	16.9" x 14.2" x 14.2"	20.3" x 17.5" x 19"	21.5" x 32.3" x 22.4"
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 tatio.	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.
Whole blood	Whole blood	Whole blood	Whole blood
Evaluates blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries.	Blood cell diseases	Blood cell diseases	Blood cell diseases
Typically 15 minutes or less.	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
Up to 5 single-cartridge tests per instrument per hour.	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
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.	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.
30 minutes to 1 hour	1 day	1.5 days	2 days
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.	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
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.	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.

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	HORIBA Medical	IMMUCOR	PixCell Medical
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1. What is the brand name of your company's hematology and/or coag analyzer?	Lite (DM) Patient Data Management System	NEO Iris	HemoScreen
2. What is the latest version of your named analyzer; what year was this version first released to market?	Lite (DM) USA 2013 FDA Class 1 Product Code OUG Medical Device Data System exempt from listing and registration	6/12/20	2018
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	Class 1 Medical device for data	FDA 510(k)	CE-Mark, 2013; FDA 510(k), 2018; TGA, 2020
4. What are the dimensions of the named product?	9" x 10" x 10"	73.2" H x 86.6" W x 35.4" D	10.2" x 6.9" x 11.8"
5. What is the intended use or primary function of the product?	Acts as middleware allowing the lab to connect their chemistry, hematology, immunoassay, and urinalysis analyzers to the LiteDM.	The NEO Iris is designed to automate standard immunohematology assays using a microplate-based platform.	Point-of-care CBC testing
6. What types of specimen/sample does the product employ?	Handles test results for any sample	Whole blood and plasma	One drop of capillary or venous blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	N/A	ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping, and antigen screening	HemoScreen analyzes 20 standard blood count parameters, delivering full and accurate CBC results
8. Under ideal conditions, what is the time to first result; how are the test results made available?	With LiteDM within 1 minute of processing samples	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.	The test takes 5 minutes and can be performed by virtually anyone. Test results are displayed on the interactive, user-friendly screen.
9. What are the product's maximum capacity and throughput under ideal conditions?	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	Up to 224 samples; multiple linear racks of 16 samples each; continuous load and unload via LED user interface	11 x 5-part differential CBC per hour or 20 x 3-part diff
10. Briefly describe any automation or connectivity features or options that pertain to the product.	The majority of chemistry, hematology, immunoassay and urinalysis analyzers can connect to the LiteDM. EMR and LIS connections are available.	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	HemoScreen is autocalibrated due to lab-on-a-cartridge technology, and enables autodetection of specimens by proprietary machine vision algorithms. .
11. What is the typical training time for the product?	1 day		1 hour
12. What types of technical support are available?	24/7 Technical Hotline support, Field Service support on-site M-F 8-5	Technical support available 24/7 and highly secure and compliant remote support through Blud_Direct.	Online training, remote diagnostics and remote intervention, remote application support, and local technical support
13. What capabilities, features, or accessories distinguish this product from others on the market?	Ability to connect up to four different analyzers. All HORIBA Medical analyzers can be connected with the following 3rd party medical devices: Abaxis Piccolo Xpress, Tosoh AIA 360, Quidel Triage, Siemens Clinitek Status, Mckesson 120.	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.	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..

Hematology & Coag Analyzers	**Scopio Labs** Tel Aviv, Israel +972 50 272 7929 lianne.trantz@scopiolabs.com www.scopiolabs.com	**Siemens Healthineers** Tarrytown, NY 469-390-7319 sheryl.kirk@siemens-healthineers.com www.siemens-healthineers.us	**Siemens Healthineers** Tarrytown, NY 469-390-7319 sheryl.kirk@siemens-healthineers.com www.siemens-healthineers.us
1. What is the brand name of your company's hematology and/or coag analyzer?	Scopio X100 series	Advia 2120i	Advia 360 Hematology System
2. What is the latest version of your named analyzer; what year was this version first released to market?	Scopio X100 - 2021	2008 US	2015 US
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2020 FDA 510(k), 2020	FDA 510(k) 2017 latest RoHS compliant	FDA 510(k) 2011
4. What are the dimensions of the named product?	12.5" x 14" x 15"	33.8" x 31.9" x 26.8" without autosampler; 33.8" x 55.5" x 26.8" with autosampler	14.4 in x 12.5 in x 19.7 in
5. What is the intended use or primary function of the product?	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
6. What types of specimen/sample does the product employ?	Whole blood	Cerebrospinal, pericardial, peritoneal, or pleural fluids; whole blood.	Whole blood
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Hematological	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	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
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Time between triggering a scan and viewing the results in the full-field PBS application is approximately 3-7 minutes, depending on selected scan mode.	30 seconds; results viewable on instrument monitor or through laboratory information system.	60 seconds; results viewable on instrument monitor or through laboratory information system
9. What are the product's maximum capacity and throughput under ideal conditions?	15-40 slides/h for complete differential (200 WBC+RBC+PLT) depending on analyzer	120 complete blood count with differential per hour	60 complete blood count with differential per hour
10. Briefly describe any automation or connectivity features or options that pertain to the product.	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.	Connection available to Aptio lab automation; automated daily maintenance; onboard specimen detection; onboard troubleshooting guides.	Bidirectional laboratory information system communication: integrated barcode reader for sample positive ID; integrated ticket printer.
11. What is the typical training time for the product?	3 hours	1 week operator training	1 day
12. What types of technical support are available?	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
13. What capabilities, features, or accessories distinguish this product from others on the market?	Includes full-field image of all clinical areas of interest including feathered edge, adaptive monolayer identification, WBC detection and pre-classification into 16 classes, RBC morphology evaluation from 1000 FOVs, PLT pre-estimation from 10 FOVs, real-time review and collaboration from anywhere.	Detection of cellular Hgb, CHCM, and CHr is unique to Advia; multispecies software for research and veterinary applications.	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

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Hematology & Coag Analyzers

	Siemens Healthineers	Sysmex America	Werfen
	Tarrytown, NY 469-390-7319 sheryl.kirk@siemens-healthineers.com www.siemens-healthineers.us	Lincolnshire, Ili hemeprodmkt@sysmex.com sysmex.com	Bedford, MA 1-800-955-9525 customerservice.na@werfen.com werfen.com
1. What is the brand name of your company's hematology and/or coag analyzer?	Advia 560 Hematology System	Sysmex XN-series analyzers	Werfen
2. What is the latest version of your named analyzer; what year was this version first released to market?	2015 US	2012	ACL TOP Family 50 Series Hemostasis Testing Systems
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k) 2011	FDA 510(k) 2012	FDA 510K (2016)
4. What are the dimensions of the named product?	52 (h) x 41 (w) x 49 (d) cm; 20 (h) x 16 (w) x 19 (d) in	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)
5. What is the intended use or primary function of the product?	Diagnosis, patient monitoring	Whole blood screening device for complete blood count and reticulocyte counting.	Diagnosis, patient monitoring, therapeutic drug monitoring.
6. What types of specimen/ sample does the product employ?	Whole blood	Whole blood	Plasma
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	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	Blood disorders	Hemophilia, Von Willebrand disease, clotting factor deficiencies, hypercoagulate states, deep venous thrombosis.
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	Varies by configuration	<3min Results appear on screen, transmitted to laboratory information system.
9. What are the product's maximum capacity and throughput under ideal conditions?	60 complete blood count with differential per hour	100 per hour per module, varies by configuration	ACL TOP 350 110 tests per hour ACL TOP 550 240 tests per hour ACL TOP 750 360 tests 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. Optional external windows compatible printer.	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.	Specialized automation workcell that intergrates all phases of hemostasis testing for optimal testing. All ACL TOP Family 50 Series systems are fully automated, equiped with liquid level sensing, intergrated barcode for true sample detection.
11. What is the typical training time for the product?	1 day	Varies by configuration	1 week operator training.
12. What types of technical support are available?	24/7/365 technical support	Remote and onsite support	24/7 comprehensive customer service and technical support
13. What capabilities, features, or accessories distinguish this product from others on the market?	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.	Scalable automation with flexibility to meet the needs of any laboratory.	ACL TOP Family 50 Series System offers unique features : tube fill height check, aspiration preassure check, test feasibility feauture, detection of interfering substances, intergrated barcode reader, HemoHub intelligent data manager.