tech guide

Hematology and Hemostasis Analyzers

	Advanced Instruments Norwood, Mass (800) 225-4034 www.aicompanies.com	Beckman Coulter Miami, Fla (305) 380-3800 www.beckmancoulter.com	Beckman Coulter Miami, Fla (305) 380-3800 www.beckmancoulter.com
1. What is the brand name of your company's hematology or hemostasis analyzer?	GloCyte automated cell counter for CSF	DxH 500 series	DxH 690T
2. What is the latest version of your named analyzer; what year was this version first released to market (US, OUS)?	2016	DxH 520.	SW 1.2; 2019 (OUS).
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TÜV CE mark, 2013; FDA 510(k), 2015).	FDA 510(k); 2016.	CE mark, 2015; FDA 510(k), 2018.	CE mark, 2019.
4. What are the dimensions of the named product (H x W x D, in inches)?	10 inches x 6 inches x 8 inches.	16 inches x 10.6 inches x 16.9 inches.	68.5 inches x 29.75 inches x 31.2 inches, excluding optional back panel.
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.	A quantitative, multiparameter, automated hematology analyzer for use in clinical laboratories.	A quantitative, multiparameter, automated hematology analyzer for screening patient populations found in clinical laboratories.
6. What types of specimen/sample does the product employ?	Cerebrospinal fluid collected from adult and pediatric patients.	Prediluted or whole blood (venous or capillary).	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?	Total nucleated cells (TNC) and red blood cells (RBC).	Hematological; identifies and enumerates the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, LY%, LY#, MO%, MO#, NE%, NE#, EO%, EO#, BA%, and BA#.	Hematological.
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.	Less than 2 minutes.	Less than 2 minutes.
9. What are the product's maximum capacity and throughput under ideal conditions?	One to two specimens in 5 minutes.	Up to 60 samples per hour.	Up to 100 samples 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 startup and instrument checks; zero hands-on daily cleaning.	Autodetection of specimens; 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 3 instruments.
11. What is the typical training time for the product?	1 hour.	Varies by region.	Can vary by region; 1 week for new users; virtual review for previous DxH users.
12. What types of technical support are available?	24/7 comprehensive customer service and technical support.	24 hour hotline; technical applications specialist for validation and adjustment questions; technical products specialist for continuing education; advanced support from Miami headquarters as needed.	24 hour hotline; technical applications specialist for validation and adjustment questions; technical products specialist for continuing education; advanced support from Miami headquarters as needed.
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.	Small 16.7 µL whole blood aspiration requirement; small footprint; requires only 2 reagents for a full CBC and differential; onboard cleaner for zero hands-on daily cleaning. Reliable instrument producing less than 1 service call per year.	Compact tabletop instrument; requires only 3 reagents for a full 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.

Beckman Coulter Miami, Fla (305) 380-3800 www.beckmancoulter.com	**Beckman Coulter** Miami, Fla (305) 380-3800 www.beckmancoulter.com	**Beckman Coulter** Miami, Fla (305) 380-3800 www.beckmancoulter.com	**Chrono-log** Havertown, Pa (800) 247-6665 www.chronolog.com
DxH 900	DxH connected workcell	DxH SMS II	Model 490 4+4 optical aggregation system
SW 1.2; 2019 (OUS).	SW 1.2; 2019 (OUS).	SW 1.2; 2019 (OUS).	Model 490 4+, Model 490 4+4; 2017.
FDA 510(k), 2018; CE mark, 2018.	FDA 510(k), 2018; CE mark, 2018.	FDA 510(k), 2018; CE mark, 2018.	FDA 510(k), 2017; CE mark, 2017.
68.5 inches x 29.75 inches x 31.2 inches, excluding optional back panel.	68.5 inches x 127.39 inches x 31.2 inches, excluding optional back panel. Width varies by configuration.	80.5 inches x 37 inches x 31 inches.	Each 4-channel module measures 8.5 inches x 14 inches x 15 inches.
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.	An automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions.	Diagnosis of platelet function defects.
Bronchoalveolar lavage fluid, cerebrospinal fluid, prediluted or whole blood (venous or capillary), serous fluids, synovial fluid.	Bronchoalveolar lavage fluid, cerebrospinal fluid, prediluted or whole blood (venous or capillary), serous fluids, synovial fluid.	Whole blood (venous or capillary) for creating a blood smear.	Platelet-rich plasma.
Hematological.	Hematological.	Hematological.	Glanzmanns thrombasthenia, primary platelet aggregation defects, storage pool and secretion defects, Von Willebrand cofactor assay, Von Willebrand disease.
Less than 2 minutes.	Less than 2 minutes.	Variable according to user requirements.	Within 2 hours for platelet-rich plasma samples.
Up to 100 samples per hour.	Up to 300 samples per hour.	Up to 140 blood smears per hour.	Platelet-rich plasma samples, up to 32 tests 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 3 instruments.	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 3 instruments.	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 3 instruments.	Requires Windows-compatible computer; includes self-calibration of optical aggregation circuits with water samples.
Can vary by region; 1 week for new users; virtual review for previous DxH users.	Can vary by region; 1 week for new users; virtual review for previous DxH users.	Can vary by region; 1 week for new users; virtual review for previous DxH users.	1 day.
24 hour hotline; technical applications specialist for validation and adjustment questions; technical products specialist for continuing education; advanced support from Miami headquarters as needed.	24 hour hotline; technical applications specialist for validation and adjustment questions; technical products specialist for continuing education; advanced support from Miami headquarters as needed.	24 hour hotline; technical applications specialist for validation and adjustment questions; technical products specialist for continuing education; advanced support from Miami headquarters as needed.	Service options: onsite, phone, email; Skype applications support: phone, email, Skype.
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. Automated ease-of-use capabilities; zero hands-on daily maintenance; remote instrument monitoring; self correction; QC auto-rerun when customized.	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. Automated ease-of-use capabilities; zero hands-on daily maintenance; remote instrument monitoring; self correction; QC auto-rerun when customized.	N/A	Provides up to 8 channels of optical aggregometry with ability to test small sample volume of 250 µL. Improved calibration of optical circuits.

Chrono-log	Diagnostica Stago	Diagnostica Stago	Diagnostica Stago
Havertown, Pa (800) 247-6665 www.chronolog.com	Parsippany, NJ (973) 631-1200 www.stago-us.com	Parsippany, NJ (973) 631-1200 www.stago-us.com	Parsippany, NJ (973) 631-1200 www.stago-us.com
Model 700 whole blood/optical lumi aggregometer	Sta-R Max	Sta Compact Max	Sta Satellite
Model 700-2, Model 700-4; 2006.	2015 (US).	2013 (US).	2009 (US).
FDA 510(k), 2005; CE mark, 2005.	FDA 510(k), 2015.	FDA 510(k), 2013.	FDA 510(k), 2008.
Each 2-channel module measures 8.5 inches x 14 inches x 18 inches.	73.8 inches x 115.7 inches x 51.1 inches.	27.75 inches x 38.1 inches x 28.73 inches.	27.4 inches x 21.1 inches x 25.5 inches.
Diagnosis of platelet function defects and monitoring of antiplatelet drugs.	A fully automatic, free-standing, high-throughput analyzer suited for high-volume laboratories. Designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.	A fully automated benchtop analyzer suited for mid-size laboratories. Designed to perform tests on human plasmas to aid in the diagnosis, management, and monitoring of coagulopathies and anticoagulant therapies.	A fully automated benchtop analyzer suited for low-volume laboratories. The analyzer is capable of simultaneously performing clotting, chromogenic, and immunologic assays on human plasma to aid in the diagnosis, management, and monitoring of coagulopathies and anticoagulant therapies.
Platelet-rich plasma or whole blood.	Plasma.	Plasma.	Plasma.
Glanzmanns thrombasthenia, primary platelet aggregation defects, storage pool and secretion defects, Von Willebrand cofactor assay, Von Willebrand disease.	Coagulopathies, anticoagulant therapies.	Coagulopathies, anticoagulant therapies.	Coagulopathies, anticoagulant therapies.
Within 15 minutes for whole blood samples; within 2 hours for platelet-rich plasma samples.	Coagulation results are completed within 4.5 to 7 minutes. Results are reported in gravimetrics specific to the assay.	Coagulation results are completed within 4.5 to 7 minutes. Results are reported in gravimetrics specific to the assay.	Average time to first result is 7 minutes. Results are reported in gravimetrics specific to the assay.
Whole blood samples, 16 tests per hour; platelet-rich plasma samples, 16 tests per hour.	PT/aPTT, 200 tests per hour; PT/aPTT/Fib, 190 tests per hour; PT/aPTT/Fib/Ddi, 165 tests per hour.	PT/aPTT, 110 tests per hour; PT/aPTT/Fib, 105 tests per hour; PT/aPTT/Fib/Ddi, 90 tests per hour.	PT/aPTT, 42 tests per hour; PT/aPTT/Fib, 36 tests per hour; PT/aPTT/Fib/Ddi, 20 tests per hour.
Requires Windows-compatible computer; includes self-calibration of optical aggregation circuits with water samples.	Integrated software provides full auto-verification, repeat/reflex testing, a comprehensive QC package, accreditation tools, automated maintenance logs, and turnaround time monitoring. Maintains 5 years of patient archives onboard. Barcoded reagent management, including international sensitivity index, to eliminate data entry; liquid level detection. Can be connected to any total lab automation line.	Integrated software provides full auto-verification, repeat/reflex testing, a comprehensive QC package, accreditation tools, automated maintenance logs, and turnaround time monitoring. Maintains 5 years of patient archives onboard. Barcoded reagent management, including international sensitivity index, to eliminate data entry; liquid level detection. Can be connected to any total lab automation line.	One- or 3-point automatic or manual calibration of WBC, HGB, RBC, PLT, MCV and MPV absolute. Connectivity to laboratory information system via USB serial 3.1. Levey-Jennings QC files. Small sample support.
1.5 days.	4.5 days.	4.5 days.	3.5 days.
Service options: onsite, phone, email; Skype applications support: phone, email, Skype.	24/7/365 service hotline; technical support specialist assistance with method verification, lot conversion studies.	24/7/365 service hotline; technical support specialist assistance with method verification, lot conversion studies.	24/7/365 service hotline; technical support specialist assistance with method verification, lot conversion studies.
A 3-in-1 instrument providing whole blood/impedance and platelet-rich plasma/optical aggregation modes, plus luminescence for measuring adenosine triphosphate (ATP) secretion from platelet-dense granules. Reusable and disposable electrodes included.	For most assays, the analyzers use a viscosity-based detection system (mechanical clot), eliminating hemolysis, icterus, and lipemia interference. The Sta Coag Expert data manager provides full traceability of all end-users, sample data, reagent utilization, QC, and maintenance.	For most assays, the analyzers use a viscosity-based detection system (mechanical clot), eliminating hemolysis, icterus, and lipemia interference. The Sta Coag Expert data manager provides full traceability of all end-users, sample data, reagent utilization, QC, and maintenance.	For most assays, the analyzers use a viscosity-based detection system (mechanical clot), eliminating hemolysis, icterus, and lipemia interference.

Diatron	**Diatron**	**EKF Diagnostics**	**EKF Diagnostics**
Budapest, Hungary +36 14 369 800 www.diatron.com	Budapest, Hungary +36 14 369 800 www.diatron.com	Boerne, Texas (830) 249-0772 www.ekfusa.com	Boerne, Texas (830) 249-0772 www.ekfusa.com
Abacus 5	Abacus 3CP	DiaSpect Tm	HemoPoint H2
2013	2013	2018	2003
CE mark, 2010; FDA 510(k), 2012.	CE mark, 2010; FDA 510(k), 2012.	FDA 510(k), 2018; CLIA waiver.	FDA 510(k), 2003; CLIA waiver.
16 inches x 20 inches x 18 inches.	12 inches x 19 inches x 14 inches.	1.5 inches x 3.5 inches x 5.9 inches.	2.5 inches x 6.2 inches x 6.4 inches.
Five-part differential hematology analyzer for measuring patients' hematological parameters, within and outside of the established reference ranges.	Three-part hematology analyzer for measuring patients' hematological parameters, within and outside of the established reference ranges.	Patient monitoring in a point-of-care setting.	Patient monitoring in a point-of-care setting.
Ethylenediaminetetraacetic acid anticoagulated venous whole blood.	Ethylenediaminetetraacetic acid anticoagulated venous whole blood.	Whole blood.	Whole blood.
Enumerates the CBC parameters 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, and PLCR.	Enumerates the parameters WBC, LYM%, LYM#, MID%, MID#, GRA%,GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, and MPV.	Anemia (hemoglobin).	Anemia (hemoglobin and hematocrit).
Time to first result is 1 minute. Results are available on color touchscreen display; printed to external printer; and uploaded to laboratory information system.	Time to first result is 1 minute. Results are available on color LCD display; printed (built-in or external printer); and uploaded to laboratory information system.	Under 2 seconds.	25 to 60 seconds.
Throughput is 60 tests per hour; data storage capacity for 100,000 results.	Throughput is 60 tests per hour; data storage capacity for 10,000 results.	One test; results within 2 seconds.	One test; results in 25 to 60 seconds.
Automated calibration of measured parameters and WBC differential scatter. Connectivity to laboratory information system via Ethernet using HL7 or RS232 serial protocol. Levey-Jennings QC files. X-B graphs. Optional autosampler and Microtainer support.	One- or 3-point automatic or manual calibration of WBC, HGB, RBC, PLT, MCV and MPV absolute. Connectivity to laboratory information system via USB serial 3.1. Levey-Jennings QC files. Small sample support.	Connects to PC via USB 2.0; factory calibrated against hemoglobincyanide (HiCN) reference method; quality control materials available.	Data management options available; factory calibrated against hemoglobincyanide (HiCN) reference method; triple quality control available, including self-test, control cuvette, and liquid controls.
1 day.	1 day.	1 hour.	1 hour.
First-line technical support by local distributors; manufacturer's technical support for training, technical advisories, software upgrades, spare parts, repairs.	First-line technical support by local distributors; manufacturer's technical support for training, technical advisories, software upgrades, spare parts, repairs.	Telephone and email technical support.	Telephone and email technical support.
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.	The system supports both open and closed sample tubes.	Uses 10 µL sample size; total precision CV ≤1.0%; measuring range 1.2 g/dL to 25.5 g/dL; 'always on' technology; reagent-free cuvettes; internal battery with 40 days or 10,000 tests continuous use; cuvette shelf life up to 2.5 years after opening.	Uses 8 µL sample size; total precision CV ≤1.5%; measuring range 0 g/dL to 20 g/dL; intuitive touchscreen; internal battery providing 100 hours continuous use; 'soft load' cuvette holder; bubble-free technology; stores 4,000 test results.

	Horiba Medical Irvine, Calif (888) 903-5001 www.horiba.com	Horiba Medical Irvine, Calif (888) 903-5001 www.horiba.com	Horiba Medical Irvine, Calif (888) 903-5001 www.horiba.com
1. What is the brand name of your company's hematology or hemostasis analyzer?	ABX Pentra XL80	ABX Pentra 60C+	ABX Micros ES 60
2. What is the latest version of your named analyzer; what year was this version first released to market (US, OUS)?	2003 (US).	2000 (US).	2014 (US).
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	FDA 510(k), 2003; CE mark, 2012.	FDA 510(k), 2000; CE mark, 2010.	FDA 510(k), 2014 and 2017; CE mark, 2015.
4. What are the dimensions of the named product (H x W x D, in inches)?	21.5 inches x 32.3 inches x 22.4 inches.	20.3 inches x 17.5 inches x 19 inches.	16.9 inches x 14.2 inches x 14.2 inches.
5. What is the intended use or primary function of the product?	A fully automated 5-part differential hematology system with an autoloader, used to test whole blood specimens in clinical laboratories.	A fully automated 5-part differential hematology system used to test whole blood specimens in clinical laboratories.	A quantitative 3-part differential automated hematology system used to test 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; identifies and enumerates the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEU%, NEU#, LYM%, LYM#, MON%, MON#, EOS%, EOS#, BAS%, and BAS#.	Blood cell diseases; identifies and enumerates the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, NEU%, NEU#, LYM%, LYM#, MON%, MON#, EOS%, EOS#, BAS%, and BAS#.	Blood cell diseases; identifies and enumerates the parameters WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, LYM%, LYM#, MON%, MON#, GRA%, and GRA#.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to results is 45 seconds. Results can be displayed, printed, or transmitted to a laboratory information system.	Time to results is 60 seconds. Results can be displayed, printed, or transmitted to a laboratory information system.	Time to results is 65 seconds. Results can be displayed, printed, or transmitted to a laboratory information system.
9. What are the product's maximum capacity and throughput under ideal conditions?	Maximum throughput is 80 samples per hour; random continuous access of the autoloader.	Maximum throughput is 60 samples per hour.	Maximum throughput is 60 open-tube samples per hour, or 50 closed-tube samples per hour.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Autoloader can simultaneously handle 10 racks of 10 tubes. An available peer-group QC program provides real-time QC for each analyzer. The instrument can operate in complete blood count (CBC) mode, and differential mode (CBC + WBC differential).	Samples are introduced thru the sample tube holder. An available peer-group QC program provides real-time QC for each analyzer. The instrument can operate in complete blood count (CBC) mode, and differential mode (CBC + WBC differential).	Samples are introduced thru the sample tube holder. An available peer-group QC program provides real-time QC for each analyzer.
11. What is the typical training time for the product?	2 days.	1.5 days.	1 day.
12. What types of technical support are available?	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00 am–5:00 pm.	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00 am–5:00 pm.	24/7 technical hotline support; field service support onsite Monday through Friday, 8:00 am–5:00 pm.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Multidistribution sampling system provides precision pipetting and requires no maintenance. Double hydrodynamic sequential system ensures accurate cell-by-cell counting. Samples are rotated 360° prior to sampling, ensuring the sample is thoroughly mixed prior to aspiration.	Multidistribution sampling system provides precision pipetting and requires no maintenance. Double hydrodynamic sequential system ensures accurate cell-by-cell counting. Connectivity with the LiteDM patient data management system.	An integrated analyzer with ticket printer, barcode reader, virtual keyboard, and color touchscreen. Connectivity with the LiteDM patient data management system.

Instrumentation Laboratory Bedford, Mass (781) 674-3221 www.instrumentationlaboratory.com	**Mindray** Mahwah, NJ (425) 881-0361 www.mindraynorthamerica.com	**Mindray** Mahwah, NJ (425) 881-0361 www.mindraynorthamerica.com	**Siemens Healthineers** Tarrytown, NY (914) 524-3678 www.usa.siemens.com/healthineers
ACL Top Family 50 series	BC-3600	BC-5390	Advia 2120i
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).	2011 (OUS); 2015 (US).	2012 (OUS); 2016 (US).	2008
FDA 510(k), 2015.	CE mark; FDA 510(k).	CE mark; FDA 510(k).	FDA 510(k), 2011.
Varies by model.	18 inches x 16 inches x 18 inches.	20.6 inches x 22.4 inches x 23.2 inches.	33.8 inches x 31.9 inches x 26.8 inches without autosampler; 33.8 inches x 55.5 inches x 26.8 inches with autosampler.
Benchtop, fully automated, random access analyzers designed specifically for use in the hemostasis laboratory for coagulation or fibrinolysis testing.	Screening and diagnosis of blood disorders.	Screening and diagnosis of blood disorders.	Diagnosis, patient monitoring.
Citrated plasma.	Ethylenediaminetetraacetic acid anticoagulated whole blood.	Ethylenediaminetetraacetic acid anticoagulated whole blood.	Cerebrospinal, pericardial, peritoneal, or pleural fluids; whole blood.
Hemostasis-based assays, including heparin-induced thrombocytopenia.	Blood component disorders such as anemia, infections, platelet functions, thalassemia, and more.	Blood component disorders such as anemia, infections, platelet functions, thalassemia, and more.	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.
PT time to result is less than 3 minutes.	1 minute per sample (including 16 parameters, 3-part differential, and 3 histograms).	1 minute per sample (including 21 parameters, 5-part differential, 3 histograms, and 1 scattergram).	30 seconds; results viewable on instrument monitor or through laboratory information system.
Varies by model, ranging from 120 to 360 PT test results per hour.	60 samples per hour.	60 samples per hour; autoloader capacity is 40 samples.	120 complete blood count with differential per hour.
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.	Uploadable QC ranges; auto-sleep setting; unidirectional transmission to laboratory information system; pushbutton maintenance procedures; color indicator for expired reagents.	Bidirectional laboratory information system connectivity; built-in autoloader; whole blood sample automixing; barcode scanner; data-management and operation software; reagent expiration indicators; pushbutton maintenance; instrument standby mode.	Connection available to Aptio lab automation; automated daily maintenance; onboard specimen detection; onboard troubleshooting guides.
4 days.	1 day (operation).	1 day (operation).	1 week operator training.
Comprehensive technical support is provided 24/7.	Hotline and onsite.	Hotline and onsite.	24/7/365 technical support.
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.	Low sample requirement; 10.4-inch color touchscreen; 40,000 patient results storage, closed-tube sampling; predilute mode for pediatric samples; various sample adaptors. Barcoded reagents; 5-minute daily start-up and maintenance; 12 QC files; only 1 maintenance reagent; 8 to 24 hours sample stability; peer QC program.	Autoloader with maximum capacity of 40 samples; sample adaptors for pediatric and predilution samples; open- and closed-tube modes; customizable patient reports; only 1 maintenance reagent; cyanide-free, nontoxic reagent; patented WBC differential and digital sheath flow technology; mean time between failures is more than 2 years.	Detection of cellular Hgb, CHCM, and CHr is unique to Advia; multispecies software for research and veterinary applications.

	Siemens Healthineers Tarrytown, NY (914) 524-3678 www.usa.siemens.com/healthineers	**Siemens Healthineers** Tarrytown, NY (914) 524-3678 www.usa.siemens.com/healthineers	**Siemens Healthineers** Tarrytown, NY (914) 524-3678 www.usa.siemens.com/healthineers
1. What is the brand name of your company's hematology or hemostasis analyzer?	Sysmex CS-5100 system	Sysmex CS-2500 system	Sysmex CA-600 system series
2. What is the latest version of your named analyzer; what year was this version first released to market (US, OUS)?	2016	2016	2012
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations (eg, TUV CE mark, 2013; FDA 510(k), 2015).	FDA 510(k), 2016.	FDA 510(k), 2016.	2012
4. What are the dimensions of the named product (H x W x D, in inches)?	50.4 inches × 40.6 inches × 45.3 inches.	27 inches × 30.6 inches × 35.2 inches.	22.5 inches × 19.5 inches × 19.5 inches.
5. What is the intended use or primary function of the product?	Fully automated blood coagulation analyzer that uses chromogenic and immunoassay methods to test plasma collected from venous blood samples in 3.2% sodium citrate tubes.	Fully automated blood coagulation analyzer that uses chromogenic and immunoassay methods to test plasma collected from venous blood samples in 3.2% sodium citrate tubes.	Fully automated blood coagulation analyzer that uses chromogenic and immunoassay methods to test plasma collected from venous blood samples in 3.2% sodium citrate tubes.
6. What types of specimen/sample does the product employ?	Plasma.	Plasma.	Plasma.
7. What types of diseases, conditions, or analytes do tests performed on the analyzer detect?	Tests for PT; APTT; fibrinogen; factors II, V, VII, VIII, IX, X, XI, XII; protein C; lupus; factor V Leiden; TT; batroxobin time; Innovance antithrombin; protein C; Innovance heparin; Innovance D-dimer; Innovance free protein S antigen; factor VIII chromogenic; plasminogen.	Tests for PT; APTT; fibrinogen; factors II, V, VII, VIII, IX, X, XI, XII; protein C; lupus; factor V Leiden; TT; batroxobin time; Innovance antithrombin; protein C; Innovance heparin; Innovance D-dimer; Innovance free protein S antigen; factor VIII chromogenic; plasminogen.	Tests for PT, APTT, fibrinogen, factors assays, TT, and batroxobin time; CA-660 system adds protein C, Innovance antithrombin, Innovance heparin, and Innovance D-dimer.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	6.5 minutes.	6.5 minutes.	7 minutes.
9. What are the product's maximum capacity and throughput under ideal conditions?	400 results per hour.	180 results per hour.	60 results per hour.
10. Briefly describe any automation or connectivity features or options that pertain to the product.	Automated sampling, preanalytical sample integrity checks, autorepeat, autodilution, autoreflex, auto QC, real-time QC, auto reagent onboard management, patient result traceability, connectivity to automation track.	Automated sampling, preanalytical sample integrity checks, autorepeat, autodilution, autoreflex, auto QC, real-time QC, auto reagent onboard management, patient result traceability.	Automated sampling, autodilution for calibration, onboard QC management, onboard reagent management, patient result traceability.
11. What is the typical training time for the product?	Approximately 6 hours per tech, including 3 days at vendor office; personalized education plan for online training.	Approximately 6 hours per tech, includes 3 days at vendor office; personalized education plan for online training.	Approximately 2 hours per tech, includes 2 days onsite; personalized education plan for online training.
12. What types of technical support are available?	24/7 customer care hotline; local technical application specialists, local customer service engineer, regional support center, headquarters service center.	24/7 customer care hotline; local technical application specialists, local customer service engineer, regional support center, headquarters service center.	24/7 customer care hotline; local technical application specialists, local customer service engineer, regional support center, headquarters service center.
13. What capabilities, features, or accessories distinguish this product from others on the market?	Simultaneous multiwavelength detection and preanalytical sample integrity checks ensure high-quality first-run results; user-friendly software on Windows 7; tilted reagent vials and point-in-space automation ready; consistency for multisite patient monitoring, with sample result traceability for in-depth audit capabilities.	Simultaneous multiwavelength detection and preanalytical sample integrity checks ensure high-quality first-run results; user-friendly software on Windows 7; tilted reagent vials and point-in-space automation ready; consistency for multisite patient monitoring, with sample result traceability for in-depth audit capabilities.	Compact footprint maximizes counter space; increases uptime and reduces service expenses. Two models to meet individual laboratory needs: CA-620 system for routine clotting-based testing; CA-660 system for clotting, chromogenic, and immunologic testing.

Siemens Healthineers Tarrytown, NY (914) 524-3678 www.usa.siemens.com/healthineers	**Streck** La Vista, Neb (800) 843-0912 www.streck.com	**Sysmex America** Lincolnshire, Ill (224) 543-9809 www.sysmex.com	**Sysmex America** Lincolnshire, Ill (224) 543-9809 www.sysmex.com
BCS XP system	Diesse Mini-Cube	Sysmex XN-series hematology analyzers	Sysmex XN-L series analyzers
2006	2016	2012 (OUS), 2018 (US).	N/A
2006	MET Labs CE mark, EN 61010, EN 61326, 2016.	FDA 510(k), 2012.	FDA 510(k), 2016.
37 inches × 49 inches × 25 inches.	7.5 inches x 5.3 inches x 0.98 inches.	Varies by configuration.	Benchtop, varies by configuration.
Fully automated blood coagulation analyzer that uses chromogenic and immunoassay methods to test plasma collected from venous blood samples in 3.2% sodium citrate tubes.	Automated instrument for determining the erythrocyte sedimentation rate of patient samples collected in EDTA tubes.	Whole blood screening device for complete blood count (CBC), and reticulocyte counting.	Whole blood screening device for complete blood count (CBC), and optional reticulocyte and body fluid counting. The device extends standardized testing to low-volume laboratories.
Plasma.	Whole blood.	Whole blood.	Whole blood; optional body fluids.
Tests for PT; APTT; fibrinogen; factors II, V, VII, VIII, IX, X, XI, XII; protein C; lupus; factor V Leiden; TT; batroxobin time; Innovance antithrombin; Innovance heparin; Innovance D-dimer; Innovance free protein S antigen; factor VIII chromogenic; plasminogen; BC VWF-ristocetin cofactor assay.	Erythrocyte sedimentation rate.	Blood disorders.	Blood disorders.
5 minutes.	Results are available in 20 minutes; system automatically prints results, stores results in onboard data archive, and transmits results to laboratory information system.	Varies by configuration.	Varies by configuration.
380 results per hour.	Random access capacity of 4 samples; runs up to 12 samples per hour.	100 tests per hour per module; varies by configuration.	Up to 60 tests per hour.
Automated sampling, autorepeat, autodilution, autoreflex, auto QC, real-time QC, auto reagent onboard management, patient result traceability.	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 total lab automation tracks, and to the Bio-Rad Variant II Turbo Link A1c analyzer. All systems feature remote instrument diagnostic capability, real-time quality control, and troubleshooting.	XN-350 is a benchtop unit featuring open-tube sampling; XN-450 is a benchtop unit featuring closed-tube cap piercing; XN-550 features a continuous feed auto loader that can hold 20 samples onboard.
Approximately 8 hours per tech, includes 3 days onsite; personalized education plan for online training.	Minimal training is required; technical services department provides a 30- to 60-minute phone tutorial prior to initial installation.	Varies by configuration; training offered virtually via live streaming.	Approximately 2 days; training offered virtually via live streaming.
24/7 customer care hotline; local technical application specialists, local customer service engineer, regional support center, headquarters service center.	Technical services department team of medical technologists available during business hours.	Remote and onsite support.	Remote and onsite support.
Designed for specialty hemostasis laboratories; user-definable calibration curve expiration and prewarning alerts; user-definable barcode utility enables customizable reagent protocols; user-friendly Windows software.	Reduces sample handling, improves turnaround time, and provides excellent correlation to the manual modified Westergren method.	Scalable automation with flexibility to meet the needs of any laboratory.	Small footprint; standardized testing with market-leading XN-series; extends XN scalability.