June 25, 2025

Sysmex America, Inc.
Yvonne Doswell
Senior Scientist
577 Aptakisic Road
Lincolnshire, Illinois 60069

Re: K250943
Trade/Device Name: Sysmex XR-Series (XR-10) Automated Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: March 28, 2025
Received: March 28, 2025

Dear Yvonne Doswell:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-bell -S

Takeesha Taylor-Bell
Deputy Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250943

Device Name

Sysmex XR-Series (XR-10) Automated Hematology Analyzer

Indications for Use *(Describe)*
The XR-Series module (XR-10) is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The XR-Series module classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IPF#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K2EDTA or K3EDTA anticoagulant, and serous and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K250943.

Submitter's name, address, telephone number, contact person, and date the summary was prepared:

Submitter's Name: Sysmex America, Inc.

Submitter's Address: 577 Aptakisic Road
Lincolnshire, IL 60069

Submitter's Contact: Yvonne Doswell
Senior Scientist, Regulatory Affairs
E-Mail: doswelly@sysmex.com
Phone: (678) 274-8024

Date 510(k) Summary Prepared: March 23, 2025

Name of the device, including the trade or proprietary name, the common or usual name, and the classification name:

Proprietary Name: Sysmex XR-Series (XR-10) Automated Hematology Analyzer

Common Name: Automated Hematology Analyzer

Regulation Description: Automated Differential Cell Counter

Regulation Section: 21 CFR 864.5220

Device Class: 2

Product Code: GKZ

Related Reagents, Controls and Calibrator:

Product Code: 81GIF
CELLPACK DCL (Diluent)
CELLPACK DST (Diluent)
CELLPACK DFL (Diluent)

Product Code: 81GGK
Lysercell WNR (Lyse)
Lysercell WDF II (Lyse)
SULFOLYSER (Lyse)

Product Code: 81KQC
Fluorocell WNR (Stain)
Fluorocell WDF (Stain)
Fluorocell RET (Stain)
Fluorocell PLT (Stain)

Product Code: 81KSA

XN CAL (Calibrator)
XN CAL PF (Calibrator)

Product Code: 81JPK
XN CHECK (Quality Control)
XN CHECK BF (Quality Control)

Product Code: 81JCB
CELLCLEAN AUTO (Detergent)

Predicate Device and 510(k) number: Sysmex XN-Series (XN-10, XN-20) Automated Hematology Analyzer, K112605

Description of the Device:

The Sysmex XR-Series module (XR-10) is a quantitative multi-parameter hematology analyzer intended to perform tests on whole blood samples collected in K_2 or K_3EDTA and body fluids (pleural, peritoneal and synovial) collected in K_2EDTA anticoagulant. The analyzers can also perform tests on CSF, which should not be collected in any anticoagulant. The XR-Series analyzer consist of four principal units: (1) One Main Units (XR-10) which aspirates, dilutes, mixes, and analyzes blood and body fluid samples; (2) Two Auto Sampler Units (SA-10, SA-01) which supply samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit.

Principles of Operation:

The XR-10 analyzer performs analysis using the following methods: RF/DC Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser and SLS-hemoglobin. The RF/DC detection method detects the size of the cells by changes in direct-current resistance and the density of the cell interior by changes in radio-frequency resistance. In the sheath flow method, cells pass through the aperture of the detector surrounded by sheath fluid. Flow cytometry is also used where a semiconductor laser beam is emitted to the cells passing through the flow cell. The forward scattered light is received by the photodiode, and the lateral scattered light and lateral fluorescent light are received by the photo multiplier tube. This light is converted into electrical pulses, thus making it possible to obtain cell information. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. The system carries out all processes automatically from aspiration of the sample to outputting results and uses Microsoft Windows Operating System.

The body fluid analysis mode of the XR-10 analyzer uses the 4 part differential scattergram and the RBC distribution obtained from a specialized analysis sequence to calculate and display the WBC (WBC-BF) counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) counts and percentages, TC-BF (Total Count) & RBC (RBC-BF) counts found in the body fluid.

Analysis results and graphics are displayed on the IPU screen. They can be printed on any of the available printers or transmitted to a host computer.

Statement of Intended Use:

The XR-Series module (XR-10) is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The XR-Series module classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IPF#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K2EDTA or K3EDTA anticoagulant, and serous and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

Summary of Substantial Equivalence:

Table 1 compares the Sysmex XR-Series (XR-10) Automated Hematology Analyzer with the XN-20 Automated Hematology analyzer.

Table 1: Comparison of the Predicate XN-20 and the Proposed Sysmex XR-Series (XR-10) Automated Hematology Analyzer

Item	Predicate Analyzer XN-Series (XN-20) K112605	Proposed Analyzer XR-Series (XR-10) K250943
Similarities		
Intended Use	The XN-Series modules (XN-10, XN-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants	The XR-Series module (XR-10) is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XR-Series module classifies and enumerates the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IPF#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K2EDTA or K3EDTA anticoagulant, and serous and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of

Item	Predicate Analyzer XN-Series (XN-20) K112605	Proposed Analyzer XR-Series (XR-10) K250943
	with CSF specimens is neither required nor recommended.	anticoagulants with CSF specimens is neither required nor recommended.
Specimen Type	Whole Blood collected in K_2 or K_3EDTA	SAME
Measurement Principle	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), Flow cytometry method using semiconductor laser SLS-Hemoglobin Method	SAME
Parameters	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV,RDW-SD, MPV, NRBC%/#, RET%/#, IRF, IPF, IPF#[1], RET-He Body Fluid Mode: WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	SAME
Reagents	CELLPACK DCL (Diluent) CELLPACK DST (Diluent) CELLPACK DFL (Diluent) Lysercell WNR (Lyse) SULFOLYSER (Lyse) Fluorocell WNR (Stain) Fluorocell WDF (Stain) Fluorocell RET (Stain) Fluorocell PLT (Stain) CELLCLEAN AUTO (Detergent)	SAME
Controls/ Calibrators	XN CAL (Calibrator) XN CAL PF (Calibrator) XN CHECK (Quality Control) XN CHECK BF (Quality Control)	SAME
Types of Analysis	Manual analysis Sampler analysis	SAME
Analysis Modes	Whole Blood mode Low WBC mode Pre-Dilution mode Body Fluid mode	SAME
Sample Aspiration/ Fluidic Pathway	Single Pathway	SAME
Measuring Channels	WNR, WDF, RBC/PLT, RET, PLT-F	SAME

Item	Predicate Analyzer XN-Series (XN-20) K112605	Proposed Analyzer XR-Series (XR-10) K250943
Throughput	Pre-Dilution mode: Approximately 90 samples/hour Body Fluid 40 samples/hour maximum	SAME
Sample Aspiration Volumes	Sampler Mode – 88 µL Manual (Closed tube) Mode – 88 µL Manual (Open tube) Mode – 88 µL Dilution Mode – 70 µL Body Fluid Mode – 88 µL	SAME
Software Specifications	Samples stored: 100,000 samples Patient information: 10,000 records Wards registered: 200 wards Doctor names registered: 200 names Analysis registration function: 2,000 records QC files: 99 files per analysis module (300 plots per file) Reagent replacement history: 5,000 records Maintenance history: 5,000 records	SAME
Differences		
Measuring Channels	WPC	Not Available
Reagents	Lysercell WDF (Lyse) Lysercell WPC (Lyse) Fluorocell WPC (Stain)	Lysercell WDF II (Lyse) Not Available Not Available
Throughput	Whole Blood Mode: 100 samples/hour maximum depending on mode used.	Whole Blood Mode: 110 samples/hour maximum depending on mode used.

Please note: Intended use for the predicate analyzer was cleared in submission K112605 (XN-Series modules XN-10, XN-20). All other information listed for the predicate analyzer refers to the XN 20 module.
[1] IPF# was added to the XN-Series under K141964.

The XR-Series (XR-10) analyzer's Indications for Use statement is similar to the predicate device with minor variation. The XR-Series (XR-10) analyzer also has similar technological characteristics to the predicate device with minor variations. Both devices measure similar parameters and utilize most of the same reagents, controls, calibrators, and cleaning detergent. The data collection software functionality, communication method with data management software functionality, monitor software, connectivity, and communication are similar to the predicate device.

In order to demonstrate that differences in technological characteristics between the subject device and predicate device do not impact safety and effectiveness, the following clinical performance studies were conducted utilizing the XR-Series (XR-10) analyzer.

Summary of Performance Testing:

Clinical testing was conducted on the XR-Series (XR-10) analyzer to show equivalent performance to the XN-20 analyzer. Testing included:

Analytical Performance

Precision (Repeatability) – Whole Blood Mode

Whole blood repeatability studies were performed to evaluate within-run imprecision of whole blood parameter results when measured in replicates of ten on Sysmex XR-Series (XR-10) analyzers at three US clinical sites. The study was conducted using residual K_2EDTA whole blood samples with concentrations targeting medical decision levels, normal and high measurement range of WBC, HGB and PLT parameters and the low, normal, and high measurement range of RBC and HCT parameters. For all other claimed parameters, testing was completed using three samples (1-3) per parameter. Testing was conducted in accordance with the CLSI EP05-A3 approved guideline. The mean, standard deviation (SD), and coefficient of variation (%CV) were calculated for each parameter. The %CV estimates were evaluated against acceptance criteria. The XR-10 met manufacturer's specifications or predefined acceptance criteria requirements. The table below summarizes results from XR-10.

Measurand	Sample	Site	N	Range	Mean	SD	CV %
WBC (10^3/µL)	MDL	01	10	0.70-0.74	0.73	0.01	1.97
		05	10	1.32-1.44	1.36	0.04	2.76
		24	10	1.17-1.28	1.23	0.03	2.44
	Normal	01	10	4.79-5.21	5.02	0.10	2.09
		05	10	5.98-6.21	6.13	0.08	1.29
		24	10	7.44-7.86	7.63	0.14	1.89
	High	01	10	101.91-103.43	102.88	0.44	0.43
		05	10	103.71-104.75	104.08	0.31	0.30
		24	10	81.04-82.39	81.88	0.49	0.60
RBC (10^6/µL)	Low	01	10	1.96-1.99	1.98	0.01	0.55
		05	10	1.97-2.03	2.01	0.02	0.79
		24	10	1.51-1.55	1.53	0.01	0.97
	Normal	01	10	4.04-4.15	4.11	0.03	0.81
		05	10	3.84-3.90	3.87	0.02	0.48
		24	10	4.69-4.85	4.75	0.05	0.96
	High	01	10	6.10-6.24	6.20	0.04	0.61
		05	10	6.04-6.27	6.12	0.07	1.17
		24	10	6.40-6.50	6.45	0.03	0.45
HGB (g/dL)	MDL	01	10	7.0-7.1	7.0	0.04	0.60
		05	10	6.2-6.3	6.3	0.05	0.77
		24	10	6.5-6.6	6.6	0.05	0.79
	Normal	01	10	13.1-13.3	13.2	0.06	0.48
		05	10	14.7-14.9	14.8	0.06	0.38
		24	10	14.3-14.6	14.4	0.11	0.73
	High	01	10	17.4-17.6	17.5	0.07	0.39
		05	10	18.7-18.9	18.9	0.07	0.38
		24	10	21.2-21.6	21.4	0.13	0.59

Measurand	Sample	Site	N	Range	Mean	SD	CV %
MCHC (g/dL)	1	01	10	28.9-29.6	29.2	0.23	0.80
		05	10	27.7-28.9	28.3	0.32	1.13
		24	10	28.5-29.3	28.8	0.26	0.92
	2	01	10	31.3-32.2	31.7	0.28	0.88
		05	10	30.4-31.4	30.8	0.31	1.02
		24	10	36.6-37.6	37.2	0.28	0.75
	3	01	10	33.8-35.1	34.5	0.36	1.03
		05	10	31.9-32.6	32.2	0.29	0.89
		24	10	38.5-40.6	39.5	0.75	1.91
PLT-I (10^3/μL)	MDL	01	10	25-29	27	1.10	4.06
		05	10	27-33	30	1.7	5.62
		24	10	19-25	22	1.81	8.32
	Normal	01	10	210-240	222	8.50	3.83
		05	10	156-164	159	3.2	2.01
		24	10	224-241	235	6.04	2.57
	High	01	10	885-931	911	15.62	1.71
		05	10	947-992	969	12.62	1.30
		24	10	754-799	768	13.69	1.78
PLT-F (10^3/μL)	MDL	01	10	7-8	8	0.42	5.41
		05	10	21-23	22	0.79	3.62
		24	10	13-15	13	0.70	5.22
	Normal	01	10	207-225	217	6.54	3.01
		05	10	167-179	172	3.03	1.76
		24	10	149-155	152	1.69	1.11
	High	01	10	1020-1052	1040	9.19	0.88
		05	10	853-886	875	10.74	1.23
		24	10	871-907	889	10.10	1.14

Measurand	Sample	Site	N	Range	Mean	SD	CV %
RDW-SD (fL)	1	01	10	42.4-43.2	42.7	0.25	0.59
		05	10	43.4-44.7	44.0	0.34	0.78
		24	10	40.6-42.3	41.4	0.63	1.52
	2	01	10	50.3-53.0	52.2	0.71	1.37
		05	10	65.4-67.1	66.2	0.51	0.77
		24	10	50.4-52.1	51.1	0.71	1.38
	3	01	10	90.2-91.7	90.7	0.48	0.53
		05	10	81.6-84.5	83.5	0.87	1.04
		24	10	68.5-72.5	70.5	1.13	1.60
RDW-CV (%)	1	01	10	13.0-13.2	13.1	0.06	0.43
		05	10	12.9-13.2	13.1	0.10	0.74
		24	10	13.2-13.4	13.2	0.07	0.51
	2	01	10	17.2-17.6	17.4	0.14	0.79
		05	10	15.4-15.6	15.5	0.07	0.43
		24	10	17.9-18.8	18.4	0.28	1.50
	3	01	10	22.2-22.7	22.5	0.13	0.59
		05	10	20.7-21.2	21.0	0.14	0.65
		24	10	23.9-24.8	24.3	0.36	1.46
MPV (fL)	1	01	10	9.1-9.5	9.3	0.13	1.34
		05	10	9.1-9.2	9.2	0.05	0.56
		24	10	8.8-9.0	8.9	0.07	0.76
	2	01	10	10.7-10.9	10.8	0.08	0.76
		05	10	11.3-12.3	11.7	0.32	2.77
		24	10	10.7-11.2	11.0	0.15	1.41
	3	01	10	14.3-14.6	14.5	0.09	0.66
		05	9	13.2-14.0	13.7	0.26	1.91
		24	10	11.5-12.4	12.0	0.28	2.35

Measurand	Sample	Site	N	Range	Mean	SD	CV %
NRBC ($10^3/\mu L$)	1	01	10	0.02-0.05	0.04	0.01	24.28
		05	10	0.03-0.05	0.04	0.01	15.06
		24	10	0.02-0.05	0.04	0.01	24.28
	2	01	10	0.82-0.90	0.85	0.03	3.17
		05	10	0.03-0.06	0.05	0.01	24.00
		24	10	0.10-0.18	0.14	0.03	20.76
	3	01	10	0.25-0.35	0.31	0.03	11.07
		05	10	0.96-1.03	0.99	0.02	2.41
		24	10	1.28-1.35	1.31	0.02	1.79
NRBC (%)	1	01	10	0.5-1.1	0.8	0.18	22.12
		05	10	0.3-0.5	0.4	0.06	15.06
		24	10	0.1-0.1	0.1	0.00	0.00
	2	01	10	1.5-1.7	1.6	0.07	4.30
		05	10	0.7-1.1	0.8	0.15	18.92
		24	10	0.1-0.2	0.2	0.04	23.42
	3	01	10	2.5-3.3	2.9	0.31	10.62
		05	10	1.8-2.0	1.9	0.06	3.29
		24	10	9.1-9.5	9.3	0.14	1.56
NEUT ($10^3/\mu L$)	1	01	10	0.34-0.43	0.39	0.03	7.93
		05	10	0.49-0.57	0.52	0.02	4.62
		24	10	0.55-0.66	0.59	0.04	6.40
	2	01	10	11.57-12.00	11.79	0.14	1.18
		05	10	12.87-13.60	13.24	0.22	1.67
		24	10	6.42-6.65	6.54	0.08	1.22
	3	01	10	88.11-90.27	88.92	0.73	0.82
		05	10	92.04-95.03	94.09	1.00	1.06
		24	10	52.36-54.67	53.58	0.65	1.21

Measurand	Sample	Site	N	Range	Mean	SD	CV %
NEUT (%)	1	01	10	14.5-14.9	14.6	0.13	0.88
		05	10	11.1-11.7	11.4	0.18	1.59
		24	10	49.4-54.5	51.9	1.55	2.99
	2	01	10	73.8-76.4	75.0	0.92	1.23
		05	10	74.2-76.8	75.5	0.89	1.18
		24	10	71.3-73.9	72.4	0.77	1.06
	3	01	10	90.9-93.9	92.5	1.04	1.12
		05	10	88.3-91.3	90.4	0.85	0.94
		24	10	86.0-89.7	87.5	1.13	1.29
LYMPH (10^3/µL)	1	01	10	0.52-0.61	0.55	0.03	5.04
		05	10	0.45-0.51	0.49	0.02	4.19
		24	10	0.58-0.71	0.64	0.05	7.13
	2	01	10	1.12-1.25	1.18	0.04	3.35
		05	10	1.44-1.75	1.59	0.09	5.71
		24	10	2.02-2.23	2.13	0.06	2.97
	3	01	10	65.70-67.84	66.67	0.77	1.16
		05	10	57.42-58.32	57.90	0.30	0.52
		24	10	5.35-5.74	5.59	0.12	2.24
LYMPH (%)	1	01	10	2.7-3.0	2.8	0.10	3.40
		05	10	6.1-6.8	6.4	0.26	4.06
		24	10	2.9-3.6	3.3	0.22	6.69
	2	01	10	11.6-13.8	12.5	0.66	5.25
		05	10	38.4-40.3	39.4	0.60	1.53
		24	10	26.3-29.9	28.0	1.01	3.61
	3	01	10	80.5-92.6	87.1	3.99	4.58
		05	10	85.9-86.4	86.2	0.17	0.20
		24	10	41.5-44.4	43.2	1.08	2.50

Measurand	Sample	Site	N	Range	Mean	SD	CV %
MONO ($10^3/\mu L$)	1	01	10	0.07-0.09	0.08	0.01	10.81
		05	10	0.22-0.35	0.27	0.04	15.26
		24	10	0.04-0.07	0.06	0.01	17.81
	2	01	10	0.92-1.09	1.01	0.05	5.31
		05	10	0.67-0.75	0.71	0.03	3.73
		24	10	0.61-0.82	0.71	0.07	10.09
	3	01	10	2.80-3.27	3.01	0.15	4.98
		05	10	1.83-2.00	1.91	0.06	3.00
		24	10	13.90-18.48	15.62	1.40	8.94
MONO (%)	1	01	10	2.7-3.2	2.9	0.15	5.24
		05	10	1.4-2.3	1.8	0.29	16.14
		24	10	4.2-7.6	5.1	1.00	19.61
	2	01	10	9.5-12.3	11.2	1.20	10.77
		05	10	8.7-11.4	9.8	0.82	8.42
		24	10	6.5-8.4	7.4	0.70	9.48
	3	01	10	51.2-54.8	53.7	1.00	1.87
		05	10	14.8-19.3	17.4	1.41	8.09
		24	10	25.0-30.2	27.3	1.83	6.71
EO ($10^3/\mu L$)	1	01	10	0.08-0.12	0.10	0.01	12.09
		05	10	0.12-0.16	0.14	0.01	7.92
		24	10	0.09-0.15	0.12	0.02	20.41
	2	01	10	0.08-0.13	0.10	0.02	16.47
		05	10	0.23-0.38	0.29	0.05	17.10
		24	10	0.19-0.28	0.23	0.03	13.12
	3	01	10	0.25-0.31	0.28	0.02	7.98
		05	10	1.96-2.15	2.03	0.05	2.67
		24	10	0.86-1.27	1.10	0.16	14.18
EO (%)	1	01	10	1.2-2.1	1.5	0.33	21.58
		05	10	0.5-0.6	0.6	0.05	9.22
		24	10	0.1-0.1	0.1	0.00	0.00
	2	01	10	1.8-2.9	2.3	0.39	17.15
		05	10	2.7-4.4	3.4	0.56	16.49
		24	10	2.2-3.1	2.7	0.32	11.98

Measurand	Sample	Site	N	Range	Mean	SD	CV %
EO (%)	3	01	10	6.1-10.6	8.0	1.61	20.06
		05	10	5.9-7.5	6.8	0.46	6.85
		24	10	3.2-5.5	4.4	0.92	20.99
IG (10^3/µL)	1	01	10	0.03-0.08	0.06	0.01	22.56
		05	10	0.03-0.06	0.04	0.01	24.43
		24	10	0.03-0.06	0.05	0.01	18.89
	2	01	10	0.33-0.55	0.48	0.07	15.67
		05	10	0.44-0.72	0.63	0.09	14.84
		24	10	0.10-0.17	0.13	0.02	15.87
	3	01	10	2.81-4.55	3.52	0.61	17.36
		05	10	4.79-6.21	5.50	0.37	6.66
		24	10	19.32-21.21	20.22	0.61	3.02
IG (%)	1	01	10	0.7-1.8	1.4	0.33	22.95
		05	10	0.5-1.0	0.7	0.16	24.42
		24	10	0.4-0.7	0.6	0.08	15.45
	2	01	10	2.2-3.9	3.4	0.56	16.34
		05	10	1.6-2.4	2.1	0.27	13.19
		24	10	2.8-5.9	4.1	1.01	25.00
	3	01	10	9.2-11.7	10.2	0.86	8.42
		05	10	9.3-12.0	10.7	0.71	6.62
		24	10	23.8-25.8	24.7	0.72	2.90
IPF (%)	1	01	10	1.7-1.9	1.8	0.08	4.43
		05	10	1.2-1.4	1.4	0.07	5.14
		24	10	0.9-1.0	0.9	0.03	3.48
	2	01	10	4.2-4.8	4.5	0.17	3.86
		05	10	6.2-6.7	6.4	0.16	2.57
		24	10	3.9-4.3	4.1	0.13	3.15
	3	01	10	18.1-18.8	18.5	0.21	1.14
		05	10	14.1-16.3	15.3	0.84	5.50
		24	10	27.6-29.4	28.5	0.46	1.63

Measurand	Sample	Site	N	Range	Mean	SD	CV %
IPF ($10^3/\mu L$)	1	01	10	0.6-1.1	0.8	0.15	17.92
		05	10	1.2-1.5	1.3	0.11	8.11
		24	10	0.7-1.0	0.8	0.10	12.28
	2	01	10	10.5-12.4	11.2	0.54	4.83
		05	10	6.2-7.2	6.7	0.32	4.80
		24	10	13.1-14.4	13.8	0.45	3.26
	3	01	10	80.5-88.3	83.6	2.42	2.89
		05	10	25.6-27.5	26.3	0.62	2.35
		24	10	34.7-37.0	35.8	0.62	1.73
RET (%)	1	01	10	0.25-0.36	0.31	0.03	11.12
		05	10	0.77-0.96	0.84	0.06	6.66
		24	10	0.28-0.37	0.31	0.03	10.33
	2	01	10	2.67-2.97	2.81	0.10	3.61
		05	10	2.23-2.44	2.32	0.07	2.95
		24	10	2.43-2.74	2.60	0.11	4.15
	3	01	10	5.31-5.88	5.59	0.16	2.84
		05	10	4.65-4.96	4.80	0.10	2.03
		24	10	8.99-10.18	9.58	0.42	4.36
RET ($10^6/\mu L$)	1	01	10	0.0049 - 0.0071	0.0061	0.00	11.36
		05	10	0.0289 - 0.0340	0.0303	0.00	5.14
		24	10	0.0068 - 0.0093	0.0077	0.00	10.79
	2	01	10	0.0913 - 0.1025	0.0964	0.00	3.47
		05	10	0.0828 - 0.0921	0.0875	0.00	3.07
		24	10	0.0774 - 0.0903	0.0829	0.00	4.49
	3	01	10	0.2523 - 0.2744	0.2597	0.01	2.94
		05	10	0.1379 - 0.1561	0.1445	0.01	3.82
		24	10	0.1694 - 0.1960	0.1826	0.01	3.94

Measurand	Sample	Site	N	Range	Mean	SD	CV %
IRF (%)	1	01	10	4.4-6.4	5.4	0.56	10.26
		05	10	2.3-3.6	3.0	0.43	14.23
		24	10	3.2-5.2	4.5	0.56	12.57
	2	01	10	23.1-25.8	24.3	0.95	3.90
		05	10	15.5-18.8	17.0	1.25	7.34
		24	10	18.4-22.3	20.7	1.38	6.66
	3	01	10	41.2-44.6	42.7	1.17	2.75
		05	10	29.9-32.4	31.3	0.91	2.90
		24	10	41.8-47.0	43.8	2.00	4.55
RET-He (pg)	1	01	10	23.6-24.8	24.3	0.39	1.59
		05	10	24.5-25.4	25.0	0.27	1.10
		24	10	24.6-25.0	24.8	0.14	0.57
	2	01	10	33.6-33.9	33.7	0.09	0.28
		05	10	33.5-34.5	34.1	0.33	0.97
		24	10	33.9-35.3	34.7	0.48	1.39
	3	01	10	40.3-40.7	40.4	0.14	0.35
		05	10	39.3-39.9	39.6	0.19	0.48
		24	10	42.8-43.6	43.1	0.29	0.67

Precision (Reproducibility) – Whole Blood Mode

Reproducibility studies were performed to evaluate within-run, between-run, between-day, between-site and total imprecision of whole blood parameter results when measured in the whole blood mode of Sysmex XR-Series (XR-10) analyzers. The study was conducted using 3 levels (Low, Normal and High) of XN CHECK whole blood control material. Each level of control material was run in triplicate, twice a day for 5 days (3 levels x 3 replicates x 2 runs x 5 days = 90 results). Testing was conducted by a minimum of two operators at three US clinical sites in accordance with the CLSI EP05-A3 approved guideline. The results were analyzed by analysis of variance (ANOVA) method. The XR-10 results met the acceptance criteria. The table below summarizes results from XR-10.

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
WBC (10^3/µL)	1	90	3.05	0.060	1.98	0.000	0.00	0.000	0.00	0.021	0.68	0.064	2.09
	2	90	6.84	0.083	1.21	0.024	0.35	0.012	0.17	0.055	0.80	0.103	1.50
	3	90	16.63	0.161	0.97	0.040	0.24	0.000	0.00	0.128	0.77	0.209	1.26
RBC (10^6/µL)	1	90	2.32	0.024	1.03	0.000	0.00	0.012	0.51	0.032	1.36	0.041	1.78
	2	90	4.23	0.031	0.73	0.005	0.12	0.018	0.42	0.043	1.02	0.056	1.33
	3	90	4.97	0.037	0.75	0.017	0.33	0.000	0.00	0.032	0.65	0.052	1.05
HGB (g/dL)	1	90	5.2	0.05	0.98	0.01	0.22	0.01	0.20	0.01	0.17	0.05	1.04
	2	90	10.9	0.07	0.68	0.01	0.10	0.00	0.00	0.01	0.13	0.08	0.70
	3	90	14.4	0.06	0.40	0.01	0.06	0.02	0.12	0.06	0.38	0.08	0.57
HCT (%)	1	90	16.1	0.21	1.30	0.08	0.51	0.08	0.52	0.36	2.25	0.43	2.70
	2	90	33.0	0.29	0.88	0.19	0.56	0.13	0.39	0.62	1.89	0.72	2.19
	3	90	42.1	0.37	0.89	0.25	0.59	0.00	0.00	0.61	1.44	0.76	1.79
MCV (fL)	1	90	69.3	0.46	0.66	0.32	0.47	0.00	0.00	0.65	0.94	0.86	1.24
	2	90	78.0	0.37	0.47	0.35	0.45	0.00	0.00	0.68	0.87	0.85	1.09
	3	90	84.8	0.33	0.39	0.23	0.27	0.07	0.08	0.72	0.85	0.83	0.97

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
MCH (pg)	1	90	22.6	0.26	1.15	0.00	0.00	0.11	0.49	0.25	1.09	0.37	1.66
	2	90	25.9	0.20	0.76	0.02	0.07	0.11	0.41	0.29	1.14	0.37	1.43
	3	90	29.0	0.22	0.77	0.07	0.24	0.03	0.11	0.26	0.89	0.35	1.21
MCHC (g/dL)	1	90	32.6	0.47	1.46	0.08	0.25	0.15	0.45	0.67	2.05	0.84	2.57
	2	90	33.1	0.30	0.90	0.14	0.42	0.14	0.41	0.65	1.96	0.74	2.24
	3	90	34.2	0.32	0.92	0.16	0.48	0.00	0.00	0.60	1.74	0.69	2.03
PLT-I (10^3/µL)	1	90	95	3.5	3.70	2.4	2.57	0.0	0.00	4.3	4.49	6.0	6.36
	2	90	248	5.1	2.06	1.8	0.73	2.9	1.16	5.7	2.29	8.3	3.37
	3	90	583	9.3	1.59	1.9	0.33	0.6	0.11	9.4	1.62	13.4	2.30
PLT-F (10^3/µL)	1	90	89	1.4	1.58	0.3	0.35	0.0	0.00	4.6	5.24	4.9	5.48
	2	90	260	2.4	0.92	1.0	0.40	1.4	0.52	16.1	6.19	16.4	6.30
	3	90	584	4.7	0.80	0.7	0.12	1.3	0.23	32.0	5.47	32.4	5.54
RDW-SD (fL)	1	90	51.9	0.50	0.86	0.00	0.00	0.20	0.41	0.30	0.65	0.60	1.15
	2	90	46.3	0.33	0.70	0.08	0.17	0.00	0.00	0.73	1.58	0.80	1.74
	3	90	52.0	0.33	0.64	0.17	0.33	0.11	0.21	0.58	1.11	0.69	1.34

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
RDW-CV (%)	1	90	21.0	0.14	0.68	0.12	0.58	0.00	0.00	0.09	0.42	0.21	0.98
	2	90	16.8	0.11	0.63	0.06	0.33	0.00	0.00	0.14	0.82	0.18	1.09
	3	90	17.3	0.10	0.59	0.02	0.09	0.02	0.13	0.23	1.30	0.25	1.44
MPV (fL)	1	90	9.0	0.17	1.88	0.00	0.00	0.04	0.42	0.12	1.28	0.21	2.31
	2	90	9.3	0.11	1.16	0.00	0.00	0.03	0.36	0.10	1.13	0.15	1.66
	3	90	9.1	0.07	0.77	0.00	0.00	0.03	0.28	0.13	1.45	0.15	1.67
NRBC ($10^3/\mu L$)	1	90	0.16	0.013	8.47	0.004	2.39	0.005	3.02	0.000	0.00	0.015	9.30
	2	90	0.42	0.020	4.64	0.000	0.00	0.007	1.70	0.000	0.00	0.021	4.94
	3	90	1.13	0.034	3.00	0.000	0.00	0.007	0.66	0.000	0.00	0.035	3.07
NRBC (%)	1	90	5.2	0.44	8.53	0.13	2.47	0.15	2.90	0.00	0.00	0.49	9.35
	2	90	6.2	0.29	4.70	0.00	0.00	0.09	1.40	0.00	0.00	0.30	4.90
	3	90	6.8	0.22	3.19	0.00	0.00	0.06	0.92	0.00	0.00	0.23	3.32
NEUT ($10^3/\mu L$)	1	90	1.19	0.039	3.26	0.000	0.00	0.008	0.69	0.000	0.00	0.040	3.33
	2	90	3.02	0.068	2.23	0.014	0.48	0.000	0.00	0.031	1.01	0.075	2.50
	3	90	7.95	0.163	2.05	0.063	0.80	0.000	0.00	0.065	0.82	0.186	2.34

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
LYMPH ($10^3/\mu L$)	1	90	1.17	0.037	3.13	0.000	0.00	0.006	0.49	0.011	0.90	0.039	3.29
	2	90	2.15	0.058	2.68	0.014	0.66	0.000	0.00	0.018	0.86	0.062	2.89
	3	90	4.42	0.080	1.82	0.000	0.00	0.000	0.00	0.036	0.81	0.088	1.99
MONO ($10^3/\mu L$)	1	90	0.26	0.016	6.33	0.000	0.00	0.000	0.00	0.000	0.00	0.016	6.33
	2	90	0.63	0.031	4.88	0.000	0.00	0.005	0.83	0.003	0.53	0.031	4.98
	3	90	1.56	0.050	3.22	0.000	0.00	0.027	1.74	0.000	0.00	0.057	3.66
EO ($10^3/\mu L$)	1	90	0.29	0.027	9.47	0.000	0.00	0.000	0.00	0.001	0.32	0.027	9.48
	2	90	0.72	0.058	8.01	0.000	0.00	0.003	0.39	0.016	2.20	0.060	8.32
	3	90	1.89	0.112	5.92	0.045	2.40	0.042	2.22	0.026	1.37	0.131	6.90
BASO ($10^3/\mu L$)	1	90	0.14	0.007	4.59	0.000	0.00	0.001	0.97	0.000	0.00	0.007	4.70
	2	90	0.33	0.010	3.17	0.000	0.00	0.003	0.88	0.003	1.01	0.011	3.44
	3	90	0.80	0.019	2.43	0.000	0.00	0.000	0.00	0.008	0.94	0.021	2.60
NEUT (%)	1	90	39.0	0.96	2.47	0.00	0.00	0.25	0.64	0.00	0.00	1.00	2.55
	2	90	44.2	0.85	1.93	0.00	0.00	0.00	0.00	0.13	0.29	0.86	1.96
	3	90	47.8	0.82	1.71	0.30	0.64	0.00	0.00	0.04	0.09	0.88	1.83

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
LYMPH (%)	1	90	38.5	1.02	2.66	0.00	0.00	0.20	0.53	0.00	0.00	1.04	2.71
	2	90	31.4	0.78	2.48	0.00	0.00	0.00	0.00	0.00	0.00	0.78	2.48
	3	90	26.6	0.38	1.42	0.02	0.09	0.00	0.00	0.06	0.24	0.38	1.44
MONO (%)	1	90	8.4	0.51	6.05	0.00	0.00	0.00	0.00	0.00	0.00	0.51	6.05
	2	90	9.1	0.42	4.57	0.00	0.00	0.03	0.32	0.00	0.00	0.42	4.58
	3	90	9.4	0.30	3.24	0.02	0.17	0.15	1.58	0.00	0.00	0.34	3.61
EO (%)	1	90	9.4	0.86	9.17	0.00	0.00	0.00	0.00	0.00	0.00	0.86	9.17
	2	90	10.5	0.83	7.93	0.00	0.00	0.10	0.96	0.25	2.39	0.88	8.34
	3	90	11.4	0.68	5.95	0.27	2.35	0.24	2.09	0.08	0.74	0.77	6.77
BASO (%)	1	90	4.7	0.20	4.15	0.00	0.00	0.04	0.94	0.02	0.33	0.20	4.27
	2	90	4.8	0.14	2.90	0.00	0.00	0.04	0.83	0.00	0.00	0.15	3.02
	3	90	4.8	0.10	2.15	0.00	0.00	0.00	0.00	0.00	0.00	0.10	2.15
IG ($10^3/\mu L$)	1	90	0.30	0.011	3.67	0.000	0.00	0.003	0.90	0.000	0.00	0.011	3.77
	2	90	0.77	0.026	3.43	0.005	0.66	0.000	0.00	0.006	0.77	0.027	3.57
	3	90	2.00	0.056	2.82	0.000	0.00	0.016	0.79	0.000	0.00	0.058	2.93

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
IG (%)	1	90	9.9	0.33	3.35	0.00	0.00	0.06	0.57	0.00	0.00	0.34	3.40
	2	90	11.2	0.34	3.04	0.00	0.00	0.00	0.00	0.00	0.00	0.34	3.04
	3	90	12.0	0.30	2.50	0.00	0.00	0.11	0.91	0.00	0.00	0.32	2.66
RET (%)	1	90	5.56	0.134	2.42	0.000	0.00	0.053	0.94	0.232	4.17	0.273	4.91
	2	90	2.35	0.075	3.21	0.011	0.48	0.000	0.00	0.095	4.02	0.122	5.17
	3	90	1.26	0.051	4.07	0.000	0.00	0.013	1.04	0.042	3.34	0.068	5.37
RET (10^6/µL)	1	90	0.1289	0.00340	2.64	0.00000	0.00	0.00118	0.91	0.00359	2.78	0.00509	3.95
	2	90	0.0994	0.00322	3.24	0.00069	0.69	0.00000	0.00	0.00322	3.23	0.00460	4.63
	3	90	0.0627	0.00260	4.14	0.00000	0.00	0.00075	1.19	0.00221	3.53	0.00349	5.57
IRF (%)	1	90	33.5	2.38	7.10	2.00	5.98	0.00	0.00	0.70	2.09	3.19	9.51
	2	90	40.3	2.21	5.49	1.55	3.85	0.00	0.00	0.72	1.78	2.80	6.94
	3	90	33.7	1.94	5.76	0.41	1.20	0.41	1.23	0.24	0.71	2.04	6.05
RET-He (pg)	1	90	24.0	0.14	0.59	0.14	0.58	0.06	0.25	0.11	0.47	0.24	0.99
	2	90	24.8	0.17	0.69	0.08	0.32	0.07	0.26	0.18	0.74	0.27	1.10
	3	90	25.8	0.25	0.98	0.00	0.00	0.06	0.25	0.23	0.90	0.35	1.35
IPF (%)	1	90	19.1	0.53	2.75	0.22	1.13	0.00	0.00	0.02	0.13	0.57	2.98
	2	90	19.8	0.65	3.29	0.00	0.00	0.00	0.00	0.28	1.41	0.71	3.58
	3	90	20.0	0.76	3.82	0.00	0.00	0.36	1.78	0.28	1.38	0.88	4.43
IPF (10^3/µL)	1	90	16.9	0.51	3.04	0.23	1.37	0.00	0.00	0.86	5.10	1.03	6.10
	2	90	51.5	1.80	3.49	0.00	0.00	0.40	0.77	2.87	5.56	3.41	6.61
	3	90	116.6	4.59	3.93	0.00	0.00	2.01	1.72	7.95	6.81	9.39	8.05

Precision (Repeatability) – Body Fluid Mode

Body fluid repeatability studies were conducted using residual peritoneal, pleural and synovial fluid samples collected in K_2EDTA anticoagulant and CSF without anticoagulant with concentrations targeting the low, and high end of the measurement range of direct measured parameters (WBC-BF, RBC-BF, TC-BF). Each sample was thoroughly mixed by gentle hand inversion and measured in replicates of ten in the body fluid mode on XR-10 analyzer at three US clinical sites. Testing was conducted in accordance with the CLSI EP05-A3 approved guideline. The mean, standard deviation (SD), and coefficient of variation (%CV) were calculated for each parameter. The %CV estimates were evaluated against acceptance criteria. The calculated coefficient of variation (%CV) of all body fluid parameters on XR-10 analyzer across all sites met manufacturer's specifications.

Precision (Reproducibility) – Body Fluid Mode

Reproducibility studies were performed to evaluate within-run, between-run, between-day, between-site and total imprecision of body fluid parameter results when measured in the body fluid mode of Sysmex XR-Series (XR-10) analyzer. The study was conducted using 2 levels (Low and High) of XN CHECK BF body fluid control material. Testing was conducted by a minimum of two operators at three US clinical sites in accordance with the CLSI EP05-A3 approved guideline. Each level of control was mixed thoroughly prior to sampling in triplicate, twice a day for 5 days (2 levels x 3 replicates x 2 runs x 5 days = 60 results per parameter) in the body fluid analysis mode on XR-10 analyzer at each site. The results were analyzed by analysis of variance (ANOVA) method. The XR-10 results met manufacturer's specifications. The table below summarizes results from XR-10.

All Sites Combined				Within Run		Between Run		Between Day		Between Site		Total Precision	
Parameter	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**%SD**	**%CV**
WBC-BF ($10^3/\mu L$)	1	90	0.073	0.0029	3.91	0.0009	1.18	0.0000	0.00	0.0006	0.82	0.0030	4.16
	2	90	0.303	0.0061	2.01	0.0000	0.00	0.0016	0.54	0.0032	1.07	0.0071	2.34
RBC-BF ($10^6/\mu L$)	1	90	0.024	0.0008	3.49	0.0000	0.00	0.0002	0.86	0.0004	1.57	0.0009	3.93
	2	90	0.073	0.0014	1.87	0.0000	0.00	0.0004	0.53	0.0011	1.51	0.0018	2.46
MN ($10^3/\mu L$)	1	90	0.021	0.0016	7.33	0.0003	1.38	0.0000	0.00	0.0001	0.49	0.0016	7.47
	2	90	0.088	0.0032	3.61	0.0000	0.00	0.0008	0.90	0.0011	1.23	0.0035	3.92
MN % (%)	1	90	29.1	1.74	5.98	0.34	1.17	0.00	0.00	0.28	0.97	1.80	6.17
	2	90	29.1	0.90	3.08	0.00	0.00	0.00	0.00	0.00	0.00	0.90	3.08
PMN ($10^3/\mu L$)	1	90	0.052	0.0023	4.50	0.0007	1.41	0.0000	0.00	0.0006	1.16	0.0025	4.86
	2	90	0.215	0.0052	2.40	0.0000	0.00	0.0000	0.00	0.0021	0.97	0.0056	2.59
PMN (%)	1	90	70.9	1.74	2.45	0.34	0.48	0.00	0.00	0.28	0.40	1.80	2.53
	2	90	70.9	0.90	1.26	0.00	0.00	0.00	0.00	0.00	0.00	0.90	1.26
TC-BF ($10^3/\mu L$)	1	90	0.073	0.0029	3.91	0.0009	1.18	0.0000	0.00	0.0006	0.82	0.0030	4.16
	2	90	0.303	0.0061	2.01	0.0000	0.00	0.0016	0.54	0.0032	1.07	0.0071	2.34

Linearity:

Whole Blood

Linearity studies were performed using WRP CHECK EX whole blood linearity material and system diluent (CELLPACK DCL). A minimum of seven sample dilutions were created with concentrations which span the full measurement range (1-level below, 5-levels within and 1-level above) of WBC, RBC, HGB, HCT, PLT-I and PLT-F directly measured parameters. All samples were mixed thoroughly prior to testing in replicates of three in the whole blood mode of three XR-10 analyzers at one internal site. Testing and analysis of the data were conducted in accordance with CLSI EP06-ED2:2020. The results of whole blood linearity for measured WBC, RBC, HGB, HCT, PLT-I and PLT-F parameters by XR-10 analyzers demonstrate the method to be linear from the lower limit to upper limit and within the measured maximum allowable deviation from linearity for each interval. All results met predefined acceptance criteria.

Parameter	Linear Range
WBC ($x10^3/\mu L$)	0.03 – 440.00
RBC ($x10^6/\mu L$)	0.01 – 8.60
HGB (g/dL)	0.1 – 26.0
HCT (%)	0.1 – 75.0
PLT($x10^3/\mu L$)	2 – 5,000
RET (%)	0.00 – 30.00

Body Fluid

Linearity studies were performed using a minimum of seven sample dilutions created with concentrations which spanned the full measurement range (1-level below, 5-levels within and 1-level above) of WBC-BF, RBC-BF and TC-BF direct measured parameters. All samples were mixed thoroughly prior to testing in replicates of three in the body fluid mode of three XR-10 analyzers at one internal site. Testing and analysis of the data were conducted in accordance with CLSI EP06-ED2:2020. The results of body fluid linearity for measured WBC-BF, RBC-BF and TC-BF parameters by XR-10 demonstrate the method to be linear from the lower limit to upper limit and is within the measured maximum allowable deviation from linearity for each interval. All results met predefined acceptance criteria.

Parameter	Linear Range
WBC-BF ($x10^3/\mu L$)	0.003 – 10.000
RBC-BF ($x10^6/\mu L$)	0.002 – 5.000
TC-BF ($x10^3/\mu L$)	0.003 – 10.000

Analytical Specificity/Interferences:

Interfering substances studies were conducted for Bilirubin F, Bilirubin C, Chyle, Hemolytic Hemoglobin, Lipids, and high WBC, RBC, and platelet counts and microcytic RBCs to determine the concentration that impact all claimed parameters on the Sysmex XR-Series Automated Hematology analyzers. Whole blood K_2EDTA samples were collected from donors for this study and varying concentrations of interferent was added to obtain concentrations. The tubes were mixed, and measurements were repeated in four consecutive batches on the XR-Series automated hematology analyzer. The following table includes the results of the study:

Interferent	Conclusion
Bilirubin F	There was no significant Bilirubin F interference up to a concentration of 40 mg/dL for all parameters.
Bilirubin C	There was no significant Bilirubin C interference up to a concentration of 40 mg/dL for all parameters.
Chyle	There was no significant Chyle interference up to a concentration of 3,600 FTU for all parameters except for the MCHC parameter. For the MCHC parameter, there was no significant interference up to a concentration of 2,880 FTU.
Hemolytic Hemoglobin	There was no significant Hemolysis interference up to a concentration of 1,000 mg/dL for all parameters except for MCH, MCHC. For the MCH parameter, there was no significant interference observed up to a concentration of 800mg/dL. For the MCHC parameter, no significant interference was observed up to a concentration of 400mg/dL.
Lipids	There was no significant Lipemia (Intralipos) interference up to a concentration of 2.00 g/dL for all parameters except for HGB, MCH, and MCHC parameters. For HGB and MCH parameters, there was no significant interference up to a concentration of 0.20 g/dL. For the MCHC parameter, there was no significant interference up to a concentration of 0.10 g/dL.
High white blood cell counts	There was no significant WBC interference up to a concentration of 360.63 x 10^3 cells/µL for all parameters.
High red blood cell counts	There was no significant RBC interference observed up to a concentration of 8.04 x 10^6 cells/µL for all parameters.
High platelet counts	There was no significant PLT interference observed up to a concentration of 1513 (PLT-I) or 1563 (PLT-F) x 10^3 cells/µL for all parameters.
Microcytic RBCs	There was no significant interference from microcytic RBCs observed for RBC, HCT or PLT (I/F) parameters with MCV values ≤70 fL.

Sample Stability:

Whole Blood Stability

The evaluation of whole blood stability was conducted at one internal site using normal and abnormal (8 unique leftover samples and 12 prospectively collected) de-identified K_2EDTA venous whole blood samples. Samples were split into two sets stored at room temperature (18-26°C) and refrigerated temperature (2-8°C). Samples were tested in duplicate at baseline (T0), 6, 24, 25, 48, 49, 72 and 73 hours at both conditions. The mean, standard deviation, mean difference and percent difference from the baseline mean of each sample result were calculated for each parameter at each time interval for both conditions. The data supports a whole blood sample stability of 24 hours at room temperature (18-26°C) and 48 hours at refrigerated temperature (2-8°C) for XR-Series (XR-10) claimed whole blood parameters.

Body Fluid Short-term Stability

The evaluation of body fluid stability was conducted at 1 external site using 12 unique de-identified leftover body fluid samples (3-CSF, 3-peritioneal, 3-pleural and 3-synovial) when stored at controlled room temperature (RT). Peritoneal, pleural and synovial body fluid samples collected in K_2EDTA anticoagulant and CSF without anticoagulant. Samples were thoroughly mixed by gentle hand inversion at least ten times, before analyzing in singlet on XR-10 analyzer. Samples were tested at baseline or zero (0) time, 1, 2, and 4 hours at RT (18-26°C) in the body fluid analysis mode.
Body fluid samples should be analyzed within 1 hour of collection on the XR-Series (XR-10) analyzer as demonstrated in the short term stability study.

Detection Limit:

Whole Blood Mode

Limits of Blank (LoB), Limit of Detection (LoD), and the Limit of Quantitation (LoQ) were determined for the direct measured WBC, RBC, HGB, HCT and PLT parameters on Sysmex XR-10 Automated Hematology Analyzers.

In LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots, to yield 120 total measurement results per parameter. To determine the LoD and LoQ, four low concentration samples were analyzed on the Sysmex XN-20 automated hematology analyzer (K112605) to assign the reference value. The low-level samples were then measured in replicates of five over a period of three days using two reagent lots, to yield 120 total measurement results per parameter across 2-XR-10 (4 samples x 5 replicates x 3 days x 1 reagent lot per analyzer = 60 results per analyzer).

The results of the LoB, LoD, and LoQ are provided in the table below.

Parameter (Unit)	Limit of Blank (LoB)	Limit of Detection (LoD)	Limit of Quantitation (LoQ)
WBC (x 10^3/µL)	0.00	0.01	0.02
RBC (x 10^6/µL)	0.00	0.01	0.01
HGB (g/dL)	0.0	0.1	0.1
HCT (%)	0.0	0.1	0.1
PLT-I (x 10^3/µL)	0	1	2
PLT-F (x 10^3/µL)	0	1	2

Body Fluid Mode

Limits of Blank (LoB), Limit of Detection (LoD), and the Limit of Quantitation (LoQ) were determined for the direct measured WBC-BF, RBC-BF and TC-BF parameters on Sysmex XR-10 Automated Hematology Analyzers.

In LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots, to yield 120 total measurement results per parameter. To determine the LoD and LoQ, four low concentration samples were analyzed on the Sysmex XN-20 automated hematology analyzer (K112605) to assign the reference value. The low-level samples were then measured in replicates of five over a period of three days using two reagent lots, to yield 120 total measurement results per parameter across 2-XR-10 (4 samples x 5 replicates x 3 days x 1 reagent lot per analyzer = 60 results per analyzer).

The results of the LoB, LoD, and LoQ are provided in the table below.

Parameter	**LoB (N=120)**	**LoD (N=120)**	**LoQ (N=120)**
WBC-BF (10^3/µL)	0.001	0.002	0.002
RBC-BF (10^6/µL)	0.000	0.002	0.002
TC-BF (10^3/µL)	0.001	0.002	0.002

Carry-Over:

Whole Blood

Three sets of carryover sequences were run on Sysmex XR-10 analyzers for each applicable parameter at three US clinical sites using de-identified leftover venous whole blood samples collected in K_2EDTA anticoagulant. For each parameter, high target concentration samples were run in replicates of three (H1, H2, H3) followed by three replicates of low target concentration samples (L1, L2, L3) in XR-10 whole blood mode. The study was conducted in accordance with CLSI H26-A2. The results of the whole blood carryover on XR-10 analyzers show all applicable parameters met the manufacturer's specifications.

Body Fluid

Carryover was conducted using de-identified peritoneal, pleural and synovial fluids collected in K_2EDTA and CSF samples without anticoagulant with high target and low target WBC-BF, RBC-BF, and TC-BF. Three sets of carryover sequences were run on Sysmex XR-10 analyzers for each applicable parameter at three US clinical sites using de-identified leftover peritoneal, pleural and synovial fluid samples collected in K_2EDTA anticoagulant and CSF without anticoagulant. For each parameter, high target concentration samples were run in replicates of three (H1, H2, H3) followed by three replicates of low target concentration samples (L1, L2, L3) in XR-Series body fluid mode. The study was conducted in accordance with CLSI H26-A2. The results of body fluid carryover on XR-10 analyzers show all applicable parameters met the manufacturer's specifications.

Comparison Studies:

Whole Blood - Method Comparison with Predicate Device

A method comparison study was conducted to assess the performance of the Sysmex XR-Series (XR-10) Automated Hematology analyzers compared to the predicate device, Sysmex XN-20 (K112605). A total of 865 unique residual whole blood samples in K_2EDTA anticoagulant from pediatrics (<21 years) and adult (≥21 years) subjects including a variety of disease states (e.g., pathological WBCs, lipemia, hyperbilirubinemia, hemoglobinopathies, thrombocytopenia, thrombocytosis, etc.) were tested across 3 US clinical sites. Twenty samples were excluded due to insufficient sample volume and operator error.

Sample demographics from all sites included 310 pediatric subjects and 551 adults and 4 subjects with age not reported. Of this total, 53.7% were male, 45.8% female and 0.5% with sex not reported. A total of 362 normal (no flags, marked as negative) whole blood samples and 500 abnormal whole blood samples (contained flags, marked as positive) were tested.

The results of the linear regression and bias analyses between the XR-10 Whole Blood Mode and XN-20 met the acceptance criteria for all applicable parameters for correlation coefficient (r) and %Bias with the exception of the calculated bias for HGB on XR-10 at one site. The bias (-2.10%, -0.3 g/dL) was slightly above the predefined bias limits (±2% or 0.2g/dL) but is well within the predefined correlation and coefficient value limits of ≥0.95 (0.9932) and is determined acceptable. An example of the results between XN-20 and XR-10 is shown below.

Correlation and Estimated Bias (Whole Blood – Combined Sites) – XN-20 vs XR-10

Measurand	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC (10^3/µL)	841	0.03 - 410.88	0.9997	1.002 (0.993, 1.010)	0.066 (-0.031, 0.163)	0.09	0.52
RBC (10^6/µL)	845	0.03 - 8.50	0.9900	1.000 (0.991, 1.009)	-0.035 (-0.075, 0.005)	-0.03	-0.83
HGB (g/dL)	843	0.2 - 25.6	0.9915	0.994 (0.986, 1.002)	-0.100 (-0.213, 0.013)	-0.2	-1.41
HCT (%)	842	0.3 – 75.0	0.9901	0.999 (0.989, 1.009)	-0.338 (-0.743, 0.067)	-0.4	-0.98
MCV (fL)	845	62.7 - 141.5	0.9922	0.980 (0.971, 0.989)	1.711 (0.881, 2.540)	-0.2	-0.19
MCH (pg)	844	17.2 - 46.6	0.9778	0.995 (0.973, 1.017)	-0.006 (-0.650, 0.637)	-0.2	-0.54
MCHC (g/dL)	844	22.2 - 41.6	0.9286	0.961 (0.921, 1.002)	1.104 (-0.181, 2.390)	-0.1	-0.38
PLT-I (10^3/µL)	842	3 - 4930	0.9991	0.989 (0.977, 1.001)	0.840 (-2.580, 4.260)	-3.0	-0.81
PLT-F (10^3/µL)	824	4 - 4748	0.9987	1.017 (0.999, 1.035)	0.393 (-4.754, 5.540)	6.0	1.81
RDW-SD (fL)	840	29.8 - 121.5	0.9959	0.965 (0.953, 0.977)	1.891 (1.306, 2.476)	0.1	0.12

Measurand	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
RDW-CV (%)	841	10.4 - 34.8	0.9947	0.985 (0.974, 0.995)	0.229 (0.078, 0.380)	-0.0	-0.06
MPV (fL)	780	8.1 - 14.7	0.9338	0.972 (0.944, 0.999)	0.085 (-0.204, 0.374)	-0.2	-2.04
NRBC (10^3/µL)	843	0 - 11.95	0.9994	1.001 (0.988, 1.014)	-0.000 (-0.002, 0.002)	0.00	0.00
NRBC (%)	843	0 - 114.3	0.9991	0.969 (0.937, 1.000)	0.026 (0.006, 0.047)	-0.0	-0.47
NEUT (10^3/µL)	834	0 - 300.11	0.9957	0.999 (0.960, 1.038)	0.063 (-0.206, 0.332)	0.05	0.52
LYMPH (10^3/µL)	834	0 - 389.35	0.9985	1.026 (0.988, 1.065)	0.120 (-0.017, 0.256)	0.24	5.19
MONO (10^3/µL)	834	0 - 71.69	0.9692	0.939 (0.823, 1.056)	-0.001 (-0.128, 0.126)	-0.11	-6.15
EO (10^3/µL)	833	0.00 - 8.11	0.9760	1.036 (0.938, 1.134)	-0.004 (-0.021, 0.014)	0.01	2.09
BASO (10^3/µL)	834	0 - 30.10	0.9832	0.836 (0.670, 1.001)	0.009 (-0.013, 0.031)	-0.04	-15.07
NEUT (%)	834	0 - 96.3	0.9925	1.001 (0.992, 1.010)	-0.077 (-0.676, 0.521)	-0.0	-0.03
LYMPH (%)	834	0 - 96.7	0.9938	1.013 (1.003, 1.023)	0.188 (-0.057, 0.433)	0.6	2.01
MONO (%)	834	0 - 79.6	0.9658	0.940 (0.898, 0.981)	0.148 (-0.201, 0.496)	-0.4	-4.50
EO (%)	833	0.0 - 47.5	0.9897	1.001 (0.970, 1.031)	0.028 (-0.030, 0.085)	0.0	1.33
BASO (%)	834	0 - 8.4	0.9417	0.865 (0.796, 0.935)	0.014 (-0.027, 0.055)	-0.1	-11.55
IG (10^3/µL)	834	0 - 155.97	0.9980	0.995 (0.967, 1.023)	-0.000 (-0.033, 0.033)	-0.01	-0.42
IG (%)	834	0 - 44.8	0.9599	0.977 (0.936, 1.018)	0.016 (-0.057, 0.090)	-0.0	-0.26

Measurand	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
RET (%)	824	0.12 - 23.10	0.9839	0.997 (0.959, 1.035)	0.031 (-0.036, 0.098)	0.02	1.06
RET (10^6/µL)	793	0.01 - 0.5460	0.9727	0.978 (0.913, 1.042)	0.002 (-0.003, 0.007)	0.0004	0.40
IRF (%)	824	0 - 56.7	0.9729	0.976 (0.955, 0.997)	-1.660 (-1.927, -1.392)	-2.1	-12.62
RET-He (pg)	822	17 - 51.3	0.9689	0.923 (0.902, 0.944)	1.294 (0.619, 1.969)	-1.2	-3.68
IPF (%)	824	0.4 - 37.9	0.9891	0.983 (0.958, 1.009)	-0.072 (-0.175, 0.031)	-0.2	-3.12
IPF (10^3/µL)	819	0.2 - 256.4	0.9876	1.036 (0.950, 1.123)	-0.666 (-1.632, 0.300)	-0.2	-1.46

Body Fluid - Method Comparison with Predicate Device

A method comparison study was conducted to assess the performance of Sysmex XR-10 Body Fluid Mode when compared to the predicate device, Sysmex XN-20 (K112605). A total of 397 residual body fluid samples at three US sites. Two samples were excluded due to insufficient sample volume. All body fluids (peritoneal, pleural, and synovial) were collected in K_2EDTA anticoagulant with exception of CSF. All Samples were run in the Body Fluid Mode in singlet on the XN-20 and within two hours on the XR- 10 analyzer. Samples covered clinical medical decision levels, and to the extent possible, of the full measuring ranges of the XR-Series analyzers. The results of the linear regression and bias analyses between XR-10, and XN-20 Body Fluid Mode for all body fluids (CSF, peritoneal, pleural and synovial) are shown below.

Fluid Type	Measurand	N	Result Range	R	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	% Mean Diff. Or SD
CSF	WBC-BF (10^3/µL)	76	0.003 - 9.178	0.9968	0.996 (0.966, 1.027)	0.001 (-0.025, 0.028)	-0.008	-0.31
	RBC-BF (10^6/µL)	61	0.002 - 4.875	0.9970	0.997 (0.986, 1.008)	0.023 (-0.020, 0.066)	0.019	1.29
	MN (10^3/µL)	70	0.003 - 4.074	0.8750	1.734 (0.729, 2.738)	-0.459 (-1.198, 0.280)	0.244	1 SD
	MN (%)	90	0.0 - 100.0	0.7984	1.013 (0.880, 1.145)	-2.053 (-6.793, 2.688)	-1.5	1 SD
	PMN (10^3/µL)	61	0.003 - 8.393	0.9862	0.952 (0.884, 1.021)	-0.044 (-0.122, 0.034)	-0.147	1 SD
	PMN% (%)	90	0.0 - 100.0	0.7984	1.013 (0.880, 1.145)	0.792 (-9.206, 10.791)	1.5	1 SD
	TC-BF (10^3/µL)	78	0.003 - 9.192	0.9968	0.997 (0.967, 1.027)	0.001 (-0.024, 0.027)	-0.006	-0.24
Peritoneal	WBC-BF (10^3/µL)	107	0.004 - 9.766	0.9989	0.996 (0.982, 1.010)	0.012 (-0.003, 0.027)	0.006	0.31
	RBC-BF (10^6/µL)	70	0.002 - 4.801	0.9996	0.999 (0.980, 1.017)	0.004 (-0.003, 0.010)	0.003	0.31
	MN (10^3/µL)	108	0.003 - 5.689	0.9571	1.120 (0.930, 1.310)	-0.019 (-0.089, 0.052)	0.048	1 SD
	MN (%)	109	0.6 - 100.0	0.9543	0.981 (0.940, 1.021)	1.411 (-0.736, 3.559)	0.3	1 SD
	PMN (10^3/µL)	97	0.003 - 8.469	0.9936	0.955 (0.902, 1.008)	0.017 (-0.015, 0.050)	-0.046	1 SD
	PMN% (%)	109	0.0 - 99.4	0.9543	0.981 (0.940, 1.021)	0.512 (-2.413, 3.437)	-0.3	1 SD
	TC-BF (10^3/µL)	107	0.004 - 9.774	0.9988	0.997 (0.982, 1.011)	0.011 (-0.005, 0.026)	0.005	0.26

Fluid Type	Measurand	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	% Mean Diff. Or SD
Pleural	WBC-BF (10^3/µL)	95	0.005 - 9.996	0.9982	1.017 (0.996, 1.038)	-0.006 (-0.033, 0.021)	0.032	1.42
	RBC-BF (10^6/µL)	72	0.002 - 4.691	0.9998	0.994 (0.986, 1.003)	0.001 (-0.002, 0.004)	-0.003	-0.41
	MN (10^3/µL)	97	0.004 - 5.240	0.9786	1.225 (1.099, 1.350)	-0.127 (-0.212, -0.041)	0.112	1 SD
	MN (%)	99	9.2 - 100.0	0.9154	1.003 (0.962, 1.044)	0.317 (-3.802, 4.437)	0.5	1 SD
	PMN (10^3/µL)	92	0.006 - 8.862	0.9882	0.937 (0.864, 1.011)	0.007 (-0.047, 0.060)	-0.083	1 SD
	PMN% (%)	99	0.0 - 90.8	0.9154	1.003 (0.962, 1.044)	-0.637 (-2.494, 1.221)	-0.5	1 SD
	TC-BF (10^3/µL)	94	0.006 - 9.437	0.9978	1.013 (0.989, 1.036)	-0.005 (-0.035, 0.024)	0.024	1.04
Synovial	WBC-BF (10^3/µL)	55	0.004 - 9.780	0.9980	1.003 (0.978, 1.027)	0.032 (-0.008, 0.072)	0.041	1.21
	RBC-BF (10^6/µL)	56	0.002 - 4.801	0.9998	0.987 (0.975, 0.999)	0.003 (0.000, 0.006)	-0.007	-0.90
	MN (10^3/µL)	61	0.004 - 4.803	0.9342	1.248 (0.943, 1.554)	-0.156 (-0.345, 0.033)	0.094	1 SD
	MN (%)	65	0.0 - 93.1	0.9460	0.995 (0.900, 1.090)	0.306 (-1.595, 2.207)	0.1	1 SD
	PMN (10^3/µL)	56	0.003 - 8.694	0.9836	0.991 (0.960, 1.023)	-0.033 (-0.144, 0.077)	-0.057	1 SD
	PMN% (%)	65	6.9 - 100.0	0.9460	0.995 (0.900, 1.090)	0.202 (-7.956, 8.361)	-0.1	1 SD
	TC-BF (10^3/µL)	55	0.004 - 9.783	0.9979	1.003 (0.978, 1.028)	0.032 (-0.010, 0.074)	0.042	1.22

Matrix Studies:

Whole Blood Anticoagulant Comparison (K_2EDTA vs. K_3EDTA)

Comparability between K_2EDTA vs. K_3EDTA anticoagulated whole blood samples on the Sysmex XR-Series (XR-10) analyzer were conducted at 1 internal site using 46 paired K_2 and K_3EDTA venous whole blood samples. Testing was run in singlet between K_2 and K_3 EDTA anticoagulant tubes from a single donor and completed within a target of 2 hours. The study was conducted in accordance with CLSI EP09-A3 approved guidelines. The results of the regression analysis and bias analyses between K_2EDTA and K_3EDTA venous whole blood samples met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the two anticoagulants

Venous Whole Blood vs. Capillary Whole Blood (K_2EDTA)

Comparability between venous whole blood and capillary whole blood samples on the Sysmex XR-Series (XR-10) analyzer was conducted using residual and prospectively collected K_2EDTA (4mL tubes) venous whole blood samples with concentrations representative of patient samples, across medical decision levels, and to the extent possible of the full analytical measurement range of direct measured parameters (WBC, RBC, HGB, HCT and PLT). The comparison study was conducted at one internal site using seventy paired venous whole blood samples. Within 2 hours of analysis of samples in the normal tube position, samples were mixed and transferred to micro-collection tubes (without anticoagulant). Then the samples were placed in the micro collection tube holder position and run in singlet in the manual mode using the same discrete test selections used for normal tube samples on XR-10 analyzer. The study was conducted in accordance with CLSI EP09-A3 approved guidelines. The K_2EDTA sample results from the 4mL tubes were compared to the corresponding results of the micro collection tube. The results of the regression analysis and bias analyses between K_2EDTA 4mL tube samples and micro collection tube samples met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the two collection tubes.

Whole Blood K_2EDTA Normal Tubes vs. Micro-collection Tube

The study was conducted using residual and prospectively collected K_2EDTA (4mL tubes) venous whole blood samples with concentrations representative of patient samples, across medical decision levels, and to the extent possible of the full analytical measurement range of direct measured parameters (WBC, RBC, HGB, HCT and PLT) of the Sysmex XR-10 analyzer. The comparison study was conducted at one internal site using seventy paired venous whole blood samples. K_2EDTA venous whole blood samples were thoroughly mixed, then placed in the normal tube holder position and run in singlet in the manual mode. Within 2 hours of analysis of samples in the normal tube position, samples were mixed and transferred to micro-collection tubes (without anticoagulant). Then the samples were placed in the micro collection tube holder position and run in singlet in the manual mode. The study was conducted in accordance with CLSI EP09-A3 approved guidelines. The results of the regression analysis and bias analyses between K_2EDTA 4mL tube samples and micro collection tube samples met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the two collection tubes.

Bridging Studies:

Whole Blood Mode to Pre-dilute Mode Comparison

Comparability between whole blood mode to pre-dilute mode was conducted at 1 internal site using 45 de-identified residual whole blood samples and system diluent to create 1:7 dilution samples. Each whole blood sample was run in singlet in the whole blood mode of the Sysmex XR-10 analyzer. Within 2 hours of analysis in the whole blood mode, a 1:7 dilution was prepared for each sample by pipetting 600 µL of system diluent (CELLPACK DCL) into 4mL plain top tubes using calibrated displacement pipettes and adding 100 µL of whole blood using a new tip to create a 1:7 dilution. Each dilution sample was mixed by gentle hand inversion and run in singlet in the pre-dilution mode. Results in the pre-dilution mode are automatically multiplied by 7 before results are displayed, no additional calculation is required. The study was conducted in accordance with CLSI EP09-A3 approved guidelines. The results from the 4mL whole blood mode sample tubes were compared to the corresponding results of the 4 mL dilution sample tubes for the same patient sample. The results of the comparison data met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the whole blood and pre-dilution modes.

Predilute Mode Normal Tube to Micro-collection Tube Comparison

The comparison study was conducted at one internal site using 40 de-identified residual whole blood samples and system diluent to create dilution samples. A 1:7 dilution was prepared for each whole blood sample by pipetting 600 µL of system diluent (CELLPACK DCL) into 4mL plain top tubes using calibrated displacement pipettes. Using a new pipette tip, 100 µL of whole blood was added to 4 mL tubes to create a 1:7 dilution for each whole blood sample. Each sample dilution was mixed by gentle hand inversion a minimum of 10 times then placed in the Normal tube holder position and analyzed in singlet in the Pre-dilution mode of the Sysmex XR-10 analyzer. Within 2 hours of analysis, the 4 mL tube dilution samples were remixed then transferred to micro collection tubes without additives, then placed in the Micro collection tube holder position and analyzed in singlet in the Pre-dilution mode. Results in the pre-dilution mode are automatically multiplied by 7 before results are displayed, no additional calculation is required. The study was conducted in accordance with CLSI EP09-A3 approved guidelines. The results from the 4mL dilution sample tubes were compared to the corresponding results of the micro collection dilution sample tubes for the same patient sample. The results of the comparison data met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the Normal and Micro collection tube holder positions on XR-Series (XR-10) analyzer.

Low WBC Mode Normal Tube to Micro collection Tube Comparison

Comparability between Low WBC Mode Normal Tube to Micro collection was conducted at one internal site using 43 residual de-identified venous whole blood samples with WBC concentrations less than 4.50 x 10^3/µL. Each whole blood sample was mixed by gentle hand inversion a minimum of 10 times then placed in the Normal tube holder position and run in singlet in the Low WBC whole blood mode of the XR-10 analyzer. Within 2 hours of analysis in the Low WBC whole blood mode, the whole blood samples were remixed then transferred to micro collection tubes without anticoagulant then placed in the Micro collection tube holder position and run in singlet in the Low WBC whole blood mode. The study was conducted in accordance with CLSI EP09-A3 approved guidelines. The results from the Low WBC whole blood Normal tube holder sample position were compared to the corresponding results of the Micro collection tube holder sample position for the same patient sample. The results of the comparison

data met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between Low WBC mode Normal tube and Micro collection tube holder positions on the XR-Series (XR-10) analyzer.

Clinical Studies:

Clinical Sensitivity and Specificity

Sensitivity/specificity studies were conducted to evaluate the flagging capabilities of the Sysmex XR-Series (XR-10) Automated Hematology analyzer using patient samples representing a variety of abnormal conditions in comparison to manual differential counts and peripheral blood smear review by experienced examiners using light microscopy (reference method) at each of the three external clinical sites from the method comparison study. Three blood film slides were prepared for each sample for manual measurement. The flagging results from Sysmex XR-10 Automated Hematology Analyzer for normal (no flags) and abnormal (flags present) were compared to manual differential counts and peripheral blood smear review using light microscopy. The distributional and morphological flagging results were also compared to those of the XN-20 (predicate device). The sensitivity, positive percent agreement (PPA), specificity, negative percent agreement (NPA) and overall percent agreement (OPA) with 95% confidence intervals (CI) were calculated for all sites combined and are presented in the following tables.

Category	Abnormal Flagging – Manual Microscopy (Reference Method)							
	N	True Positive (TP)	False Positive (FP)	True Negative (TN)	False Negative (FN)	Sensitivity (95% CI)	Specificity (95% CI)	OPA (95% CI)
Any Distributional Abnormalities	705	325	55	213	112	74.37 (70.01 – 78.40)	79.48 (74.14 – 84.15)	76.31 (73.00 – 79.41)
Any Morphological Flag	780	199	188	353	40	83.26 (77.91 - 87.77)	65.25 (61.07 - 69.26)	70.77 (67.44 - 73.94)
Any Distributional and/or Morphological Abnormalities	780	417	102	171	90	82.25 (78.62 – 85.48)	62.64 (56.60 – 68.39)	75.38 (72.20 – 78.37)

Category	Abnormal Flagging – XN-20 (Predicate Method)							
	N	True Positive (TP)	False Positive (FP)	True Negative (TN)	False Negative (FN)	PPA (95% CI)	NPA (95% CI)	OPA (95% CI)
Any Distributional Abnormalities	834	468	14	326	26	94.74 (92.38 – 96.53)	95.88 (93.19 – 97.73)	95.20 (93.53 – 96.55)
Any Morphological Flag	844	383	60	369	32	92.29 (89.29 – 94.67)	86.01 (82.37 – 89.15)	89.10 (86.80 – 91.12)
Any Distributional and/or Morphological Abnormalities	845	557	32	235	21	96.37 (94.50 – 97.74)	88.01 (83.50 – 91.66)	93.73 (91.88 – 95.27)

Expected Values/Reference Range:

Whole Blood - Verification of Adult Reference Intervals

Verification of adult reference intervals was conducted on the Sysmex XR-Series (XR-10) Automated Hematology analyzer to demonstrate comparability of whole blood reference intervals for an adult population (>21 years) to ranges established for a predicate device Sysmex XE-5000 (K071967). One hundred and thirty-two samples (58 males and 74 females) were tested and compared to pre-established reference intervals to determine if the ranges were applicable for use with Sysmex XR-10 Automated Hematology analyzers. The results of the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the adult male and female and were determined to be acceptable.

Whole Blood - Verification of Pediatric Reference Intervals

Using Pediatric Reference Interval literature source (Wong, E., Brugnara, C., Straseski, J., Kellogg, M., & Adeli, K. 2021. Pediatric Reference Intervals. 8th ed., Hematology Tests (pp. 209-267), Academic Press.), reference interval verification study was performed for the pediatric population. A total of 196 pediatric samples including each subpopulation: 40 neonates (birth–28 days); 55 infants (>28 days–2 years); 60 children (>2 years–12 years); and 41 adolescents (>12 years–21 years) were used in the study. The results of the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the pediatric datasets from XR-10 for all parameters.

Body Fluid – Verification of Reference Intervals

A verification study was conducted using a minimum of 20 normal CSF and 20 normal Synovial fluids to verify normal reference ranges cited from published literature (Kjeldsberg's Body Fluids, Third Edition (1993). Reference intervals for other body fluid types have not been established. According to Kjeldsberg (1193), reference intervals for RBC counts are not applicable in body fluid, and therefore, no reference interval for RBC has been established.

Conclusions:

The XR-Series (XR-10) Automated Hematology analyzer and its predicate device, XN-20 Automated Hematology analyzer (K112605), have similar indications for use, fundamental technology, and principles of operation.

Performance, verification, and validation testing were conducted to characterize the performance of the XR-Series (XR-10) analyzer using predetermined acceptance criteria. Results of this testing have demonstrated that the XR-Series (XR-10) analyzer is substantially equivalent to the XN-20 analyzer.

The differences in the XR-Series (XR-10) analyzer and the predicate device (XN-20 analyzer) do not raise any questions regarding safety and effectiveness.