May 27, 2026

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

Re: K253212
Trade/Device Name: XR-Series System Configurations
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 17, 2026
Received: April 20, 2026

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

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)*
K253212

Device Name
XR-Series System Configurations

Indications for Use *(Describe)*

The XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000) are a family of integrated modular quantitative multi-parameter, automated hematology analyzer configurations intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The XR Series System Configurations consist of one or more XR-Series automated hematology analyzers (XR-10 and/or XR-20) and may include an automated slide preparation unit (SP-50). The XR-2000 configuration consists of two XR-Series automated hematology analyzers (XR-10 and/or XR-20), the XR-1500/XR-3000 configurations consist of up to two XR-Series automated hematology analyzers (XR-10 and/or XR-20) and an automated slide preparation unit (SP-50), and the XR-9000 configuration consists of up to nine XR-Series automated hematology analyzers (XR-10 and/or XR-20) and an automated slide preparation unit (SP-50).

The XR-Series analyzer modules (XR-10, XR-20) classify and enumerate 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.

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: K253212.

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: April 17, 2026

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

Proprietary Name:	XR-Series System Configurations
Common Name:	Automated Hematology Analyzer
Regulation Description:	Automated Differential Cell Counter
Regulation Section:	21 CFR 864.5220
Device Class: Product Code:	2 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 WPC* (Lyse)
Lysercell WDF II (Lyse)
SULFOLYSER (Lyse)

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

Fluorocell WPC* (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)

*For use with XR-20 only

Predicate Device(s) and 510(k) number(s): Sysmex XR-Series (XR-10) Automated Hematology Analyzer (K250943), and the Sysmex XR-Series (XR-20) Automated Hematology Analyzer (K251371).

Description of the Device:

The Sysmex® XR-Series System Configurations (XR-1500, XR-2000, XR-3000, and XR-9000) are a family of integrated modular quantitative multi-parameter, automated hematology analyzer configurations. The family of XR-Series system configurations are designed to meet the specific workflow and workload needs of clinical laboratories. The following details the components of the system configurations, their specifications, and principles of operation.

Configuration Components:

The XR-Series system configurations are comprised of the previously cleared XR-Series analyzers (XR-10 and XR-20), and the legally marketed SP-50 Slide Preparation Unit and connecting components:

- **Sysmex® XR-Series analyzer modules (XR-10, XR-20):** These are quantitative multi-parameter automated hematology analyzers intended for in vitro diagnostic use. They classify and enumerate a broad range of hematology parameters in whole blood and body fluids. The full device descriptions, principles of operation, reagents, and specifications for the standalone XR-10 and XR-20 analyzers are available in their respective 510(k) submissions (K250943 and K25137, respectively).

- **SP-50 Automated Hematology Slide Preparation Unit:** This instrument automatically prepares smears used for hematologic analysis performed by clinical laboratories. The instrument automates the processes of aspirating a sample from a sample tube, creating a smear on a glass slide, and staining the smear. The integrated SP-50 is a legally marketed Class I medical device (21 CFR 864.3800, Product Code KPA).

XR-Series System Configurations:

The following configurations represent the XR-Series System Configurations that are the subject of this submission:

- **XR-1500**: This system configuration includes one XR-10 or XR-20 analyzer with an SA-21 Auto Sampler and an SP-50 Slide Preparation Unit.
- **XR-2000**: This system configuration includes two XR-10 or XR-20 analyzers (or one of each) with an SA-20 Auto Sampler.
- **XR-3000:** This system configuration includes two XR-10 or XR-20 analyzers (or one of each) with an SA-31 Auto Sampler and an SP-50 Slide Preparation Unit.
- **XR-9000:** This system configuration may include up to nine analyzers, which include: at least two XR-Series analyzers, one SP-50 slide preparation units, one or more conveyors (CV) for physical transport, and a BT- 40 Barcode Terminal.

System Connectivity and Control:

- **Hardware Connection:** The analyzers are physically connected via hardware, including transportation units and conveyors, which automatically move sample racks between the different modules.

- **Software Connection:** The connection and integration process control are accomplished by software. This software provides data consolidation, sample transport, and process control to the various instruments in the system to improve laboratory efficiency.

Principles of Operation:

The XR-Series System Configurations (XR-1500, XR-2000, XR-3000, and XR-9000) utilize the same principles of operation, reagents, controls, and calibrators as the standalone predicate devices (K250493 and K251371). The integrated system automates the workflow steps between the instruments.

Statement of Intended Use:
The XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000) are a family of integrated modular, automated hematology analyzer configurations intended for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The XR Series System Configurations consist of one or more XR-Series automated hematology analyzers (XR-10 and/or XR-20) and may include an automated slide preparation unit (SP-50). The XR-2000 configuration consists of two XR-Series automated hematology analyzers (XR-10 and/or XR-20), the XR-1500/XR-3000 configurations consist of up to two XR-Series automated hematology analyzers (XR-10 and/or XR-20) and an automated slide preparation unit (SP-50), and the XR-9000 configuration consists of up to nine XR-Series automated hematology analyzers (XR-10 and/or XR-20) and an automated slide preparation unit (SP-50).

The XR-Series analyzer modules (XR-10, XR-20) classify and enumerate 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: Comparison of the Predicate standalone XR-10 and XR-20 Automated Hematology Analyzers and the Proposed XR-Series System Configurations

Predicates & Proposed Devices:	Predicates XR-Series (XR-10) K250943 & XR-Series (XR-20) K251371	Proposed XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000)
Device Trade Names	Sysmex XR-Series (XR-10, XR-20) Automated Hematology Analyzers	XR-Series Automated Hematology Analyzer System Configurations
General Device Characteristic Similarities		
Intended Use/Indications For Use	The XR-Series modules (XR-10, XR-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XR-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (PLT-I, PLT-F), NEUT%/#, YMPH%/#, MONO%/#, EO%/#, ASO%/#, 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.	The XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000) are a family of integrated modular quantitative multi-parameter, automated hematology analyzer configurations intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XR Series System Configurations consists of one or more XR-Series automated hematology analyzers (XR-10 and/or XR-20) and may include an automated slide preparation unit (SP-50). The XR-Series analyzer modules (XR-10, XR-20) classify and enumerate 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.
Specimen Type	Whole Blood collected in K2EDTA or K3EDTA Body fluids (serous and synovial fluids in K2EDTA anticoagulant) and CSF	Same as predicates

Predicates & Proposed Devices:	Predicates XR-Series (XR-10) K250943 & XR-Series (XR-20) K251371	Proposed XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000)
General Device Characteristic Similarities		
Measurement Principle	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), Flow cytometry method using semiconductor laser SLS- Hemoglobin Method	Same as predicates
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 as predicates
Reagents	CELLPACK DCL (Diluent) CELLPACK DST (Diluent) CELLPACK DFL (Diluent) Lysercell WNR (Lyse) Lysercell WPC* (Lyse) SULFOLYSER (Lyse) Fluorocell WNR (Stain) Fluorocell WDF (Stain) Fluorocell RET (Stain) Fluorocell PLT (Stain) Fluorocell WPC* (Stain) CELLCLEAN AUTO (Detergent) *For use with XR-20 only	Same as predicates

Predicates & Proposed Devices:	Predicates XR-Series (XR-10) K250943 & XR-Series (XR-20) K251371	Proposed XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000)
General Device Characteristic Similarities		
Controls/Calibrators	XN CAL (Calibrator) XN CAL PF (Calibrator) XN CHECK (Quality Control) XN CHECK BF (Quality Control)	Same as predicates
Type of Analysis	Manual analysis Sampler analysis	Same as predicates
Analysis Modes	Whole Blood mode Low WBC mode Pre-Dilution mode Body Fluid mode	Same as predicates
Sample Aspiration/Fluidic Pathway	Single Pathway	Same as predicates
Measuring Channels	WNR, WDF, WPC*, RBC/PLT, RET and PLT-F *For use with XR-20 only	Same as predicates
Throughput	Pre-Dilution mode: Approximately 90 samples/hour Body Fluid: 40 samples/hour maximum	Same as predicates
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 as predicates

Predicates & Proposed Devices:	Predicates XR-Series (XR-10) K250943 & XR-Series (XR-20) K251371	Proposed XR-Series System Configurations (XR-1500, XR-2000, XR-3000 and XR-9000)
General Device Characteristic Similarities		
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 as predicates
Software Version	2.03-00	Same as predicates
General Device Characteristic Differences		
System Configurations	Standalone analyzers.	An integrated system that connects the cleared XR-10 and XR-20 analyzers with the Class I SP-50 Automated Hematology Slide Preparation Unit and sample transport system via hardware and software integration.
Workstation	Each standalone analyzer is managed by its own dedicated information processing unit (IPU).	The entire system is managed by a single central Information Processing Unit (IPU).

Table 2: Comparison of Manual Differential Method and SP-50 Automated Slide Preparation Unit

Item	WBC Manual Differential Method (CLSI H20-A2:2007)	SP-50 Slide Preparation Unit
Device Trade Names	Not Applicable	Sysmex® SP-50 Automated Hematology Slide Preparation Unit
Indications for Use	Manual preparation of whole blood smears on microscopic slides using a variety of fixatives, stains, buffers, and rinse solutions.	The SP-50 Slide Preparation Unit automatically prepares smears used for hematologic analysis performed by clinical laboratories. The instrument automates the processes of aspirating a sample from a sample tube, creating a smear on a glass slide, and staining the smear.
Device Classification & Product Code	Not Applicable	Class I, 21 CFR 864.3800 Automated slide stainer Product Code: KPA
Manufacturer	Not Applicable	Sysmex Corporation
Specimen Collection	Venous whole blood in K2EDTA or K3EDTA anticoagulant	Same
Blood Film Preparation	Manually prepared by technician	Automatically prepared by SP-50 Slide Preparation Unit
Blood Film Requirements	Section 6.3.1 of CLSI H20-A2:2007	Same

The XR-Series System Configurations with the integrated XR-Series Automated Hematology Analyzers (XR-10 and XR-20) and Class I SP-50 Automated Hematology Slide Preparation Unit have similar Indications for Use statements as the standalone predicate XR-10 and XR-20 analyzers. The system configurations measure the same parameters and utilize the same reagents, controls, calibrators, and cleaning detergent.

The following performance studies were conducted utilizing the XR-Series (XR-10 and XR-20) automated hematology analyzers integrated within XR-Series XR-9000 system configurations.

Summary of Performance Testing:

Representative XR-9000 configurations were tested.

Analytical Performance:

Precision (Repeatability) – Whole Blood Mode

Whole blood repeatability studies were performed to evaluate within-run imprecision of whole blood parameter results on the integrated XR-10 and XR-20 analyzers at one internal US site.

Testing was conducted in accordance with the CLSI EP05-A3 guideline. The mean, standard deviation (SD), and coefficient of variation (%CV) were calculated for each parameter. The %CV estimates were evaluated against acceptance criteria. Both XR-10 and XR-20 have similar results and met manufacturer's specifications or predefined acceptance criteria requirements. The tables below summarize results from the integrated analyzers.

Table 1. XR-9000 Study (XR-10 Line) Whole Blood Precision Study - Repeatability

Measurand	Sample	N	Range	Mean	SD	CV %
WBC (10^3/µL)	MDL	10	1.33 – 1.43	1.40	0.04	2.61
	Normal	10	9.95 - 10.22	10.06	0.086	0.86
	High	10	92.37 - 93.61	92.89	0.407	0.44
RBC (10^6/µL)	Low	10	2.17 - 2.23	2.20	0.017	0.78
	Normal	10	4.40 - 4.49	4.43	0.026	0.59
	High	10	6.34 - 6.45	6.41	0.032	0.50
HGB (g/dL)	MDL	10	6.6 - 6.7	6.7	0.05	0.78
	Normal	10	15.1 - 15.3	15.2	0.06	0.37
	High	10	18.1 - 18.3	18.2	0.08	0.43

Measurand	Sample	N	Range	Mean	SD	CV %
HCT (%)	Low	10	24.8 - 25.0	24.9	0.09	0.35
	Normal	10	45.1 - 45.7	45.4	0.21	0.46
	High	10	51.2 - 52.6	51.8	0.45	0.86
MCV (fL)	1	10	79.9 - 81.9	80.8	0.71	0.88
	2	10	90.4 - 91.4	90.7	0.28	0.30
	3	10	98.2 - 98.6	98.4	0.16	0.16
MCH (pg)	1	10	28.4 - 29.3	28.8	0.31	1.07
	2	10	30.1 - 30.7	30.4	0.19	0.61
	3	10	32.7 - 33.3	32.9	0.21	0.65
MCHC (g/dL)	1	10	31.5 - 32.4	32.0	0.29	0.91
	2	10	32.7 - 33.3	33.1	0.21	0.62
	3	10	34.6 - 35.7	35.2	0.32	0.91
PLT-I (10^3/µL)	MDL	10	26 - 32	29	1.8	6.24
	Normal	10	161 - 176	169	4.7	2.79
	High	10	681 - 719	699	14.0	2.00
PLT-F (10^3/µL)	MDL	10	27 - 29	29	0.7	2.48
	Normal	10	169 - 176	172	2.4	1.37
	High	10	736 - 748	742	3.4	0.46
RDW-SD (fL)	1	10	37.2 - 39.1	38.2	0.62	1.63
	2	10	48.5 - 49.4	49.0	0.24	0.50
	3	10	66.4 - 67.6	67.1	0.41	0.61
RDW-CV (%)	1	10	11.9 - 12.0	12.0	0.05	0.43
	2	10	14.9 - 15.3	15.1	0.13	0.84
	3	10	19.2 - 19.4	19.3	0.06	0.33
MPV (fL)	1	10	8.8 - 9.3	9.1	0.17	1.86
	2	10	9.7 - 10.1	10.0	0.13	1.29
	3	10	11.8 - 12.9	12.4	0.31	2.53

Measurand	Sample	N	Range	Mean	SD	CV %
NRBC (10^3/µL)	1	10	0.00 - 0.05	0.02	0.019	118.59
	2	10	0.02 - 0.04	0.03	0.009	30.19
	3	10	0.00 - 0.08	0.04	0.023	63.07
NRBC (%)	1	10	0.0 - 0.1	0.1	0.05	86.07
	2	10	0.0 - 1.0	0.3	0.38	118.59
	3	10	0.0 - 1.5	0.7	0.42	60.23
NEUT (10^3/µL)	1	10	2.79 - 2.96	2.87	0.064	2.24
	2	10	7.30 - 7.60	7.47	0.089	1.19
	3	10	24.98 - 26.37	25.61	0.456	1.78
NEUT (%)	1	10	47.5 - 49.6	48.6	0.73	1.51
	2	10	58.8 - 61.4	60.2	0.77	1.28
	3	10	73.4 - 74.9	74.2	0.44	0.59
LYMPH (10^3/µL)	1	10	1.10 - 1.23	1.18	0.041	3.45
	2	10	4.21 - 4.70	4.49	0.137	3.05
	3	10	91.50 - 92.79	92.13	0.413	0.45
LYMPH (%)	1	10	8.3 - 9.3	8.9	0.28	3.18
	2	10	30.1 - 33.4	31.5	0.88	2.80
	3	10	99.1 - 99.3	99.2	0.09	0.09
MONO (10^3/µL)	1	10	0.08 - 0.11	0.10	0.008	8.95
	2	10	0.54 - 0.65	0.60	0.035	5.81
	3	10	6.96 - 9.01	8.05	0.584	7.26
MONO (%)	1	10	5.0 - 5.7	5.3	0.22	4.14
	2	10	16.0 - 20.0	18.0	1.33	7.38
	3	10	37.5 - 55.0	46.4	6.42	13.83
EO (10^3/µL)	1	10	0.09 - 0.16	0.12	0.022	18.04
	2	10	0.25 - 0.33	0.30	0.023	7.87
	3	10	0.68 - 0.75	0.72	0.022	3.07

Measurand	Sample	N	Range	Mean	SD	CV %
EO (%)	1	10	0.9 - 1.6	1.2	0.22	18.04
	2	10	1.4 - 1.5	1.5	0.05	3.63
	3	10	3.6 - 4.6	4.2	0.29	6.83
BASO ($10^3/\mu L$)	1	10	0.02 - 0.04	0.03	0.007	20.45
	2	10	0.05 - 0.07	0.06	0.007	10.71
	3	10	0.12 - 0.15	0.13	0.011	7.97
BASO (%)	1	10	0.3 - 0.5	0.4	0.07	20.20
	2	10	0.7 - 1.0	0.9	0.11	11.71
	3	10	2.3 - 2.8	2.5	0.19	7.44
IG ($10^3/\mu L$)	1	10	0.06 - 0.11	0.08	0.015	20.12
	2	10	0.09 - 0.15	0.12	0.018	15.47
	3	10	10.81 - 12.21	11.50	0.385	3.35
IG (%)	1	10	0.9 - 1.5	1.2	0.18	15.47
	2	10	1.1 - 2.1	1.4	0.29	20.41
	3	10	21.3 - 24.1	22.8	0.76	3.33
IPF ($10^3/\mu L$)	1	10	0.3 - 0.5	0.4	0.08	18.78
	2	10	3.7 - 4.4	4.0	0.19	4.66
	3	10	10.1 - 12.4	11.3	0.64	5.69
IPF (%)	1	10	1.0 - 1.2	1.1	0.07	6.73
	2	10	5.3 - 6.3	5.7	0.33	5.82
	3	10	9.6 - 11.6	10.4	0.53	5.09
RET (%)	1	10	0.32 - 0.43	0.37	0.031	8.35
	2	10	1.99 - 2.17	2.08	0.052	2.49
	3	10	4.17 - 4.79	4.53	0.178	3.93
RET ($10^6/\mu L$)	1	10	0.0031 - 0.0048	0.0039	0.00045	11.59
	2	10	0.0999 - 0.1083	0.1042	0.00248	2.38
	3	10	0.1835 - 0.2122	0.2006	0.00834	4.16

Measurand	Sample	N	Range	Mean	SD	CV %
IRF (%)	1	10	5.8 - 12.5	9.9	2.11	21.43
	2	10	11.1 - 15.3	12.8	1.38	10.79
	3	10	21.6 - 25.8	23.6	1.46	6.21
RET-He (pg)	1	10	31.8 - 32.8	32.3	0.34	1.05
	2	10	36.0 - 37.0	36.6	0.28	0.77
	3	10	42.5 - 47.0	43.8	1.38	3.15

Table 2. XR-9000 Study (XR-20 Line) Whole Blood Precision Study - Repeatability

Measurand	Sample	N	Range	Mean	SD	CV %
WBC ($10^3/\mu L$)	MDL	10	1.70 - 1.83	1.77	0.037	2.11
	Normal	10	7.77 - 8.13	7.94	0.096	1.21
	High	10	60.90 - 61.76	61.35	0.348	0.57
RBC ($10^6/\mu L$)	Low	10	2.18 - 2.23	2.20	0.013	0.57
	Normal	10	4.63 - 4.71	4.67	0.023	0.49
	High	10	6.36 - 6.49	6.42	0.039	0.61
HGB (g/dL)	MDL	10	7.8 - 7.9	7.9	0.04	0.54
	Normal	10	13.6 - 13.8	13.8	0.07	0.51
	High	10	18.3 - 18.5	18.4	0.06	0.34
HCT (%)	Low	10	23.2 - 23.6	23.3	0.13	0.55
	Normal	10	39.8 - 40.4	40.1	0.16	0.39
	High	10	53.9 - 55.0	54.4	0.32	0.59
MCV (fL)	1	10	84.7 - 85.0	84.8	0.10	0.12
	2	10	90.2 - 90.6	90.4	0.16	0.17
	3	10	105.4 - 106.4	105.7	0.31	0.29
MCH (pg)	1	10	28.9 - 29.6	29.2	0.23	0.78
	2	10	29.9 - 30.6	30.3	0.20	0.65
	3	10	36.5 - 37.8	37.3	0.39	1.04
MCHC (g/dL)	1	10	31.1 - 32.1	31.5	0.30	0.95
	2	10	34.2 - 35.0	34.5	0.25	0.71
	3	10	36.9 - 38.5	37.7	0.41	1.09
	MDL	10	8 - 10	9	0.7	8.11

Measurand	Sample	N	Range	Mean	SD	CV %
PLT-I (10^3/µL)	Normal	10	211 - 222	215	3.6	1.70
	High	10	587 - 616	604	7.9	1.31
PLT-F (10^3/µL)	MDL	10	12 – 13	12	0.5	3.93
	Normal	10	226 - 233	230	2.1	0.89
	High	10	695 - 707	702	3.7	0.53
RDW-SD (fL)	1	10	40.8 - 42.0	41.3	0.41	0.98
	2	10	55.0 - 56.6	55.5	0.49	0.88
	3	10	60.2 - 61.5	60.8	0.37	0.61
RDW-CV (%)	1	10	12.8 - 12.9	12.9	0.05	0.38
	2	10	13.9 - 14.1	14.0	0.07	0.53
	3	10	17.6 - 17.9	17.7	0.08	0.46
MPV (fL)	1	10	8.6 - 8.7	8.6	0.05	0.56
	2	10	9.9 - 10.2	10.1	0.12	1.22
	3	10	11.6 - 11.9	11.7	0.09	0.75
NRBC (10^3/µL)	1	10	0.00 - 0.09	0.05	0.030	65.63
	2	10	0.03 - 0.11	0.06	0.025	43.62
	3	10	0.06 - 0.17	0.11	0.039	36.08
NRBC (%)	1	10	0.0 - 0.2	0.1	0.06	63.07
	2	10	0.0 - 0.9	0.4	0.30	86.50
	3	10	0.0 - 3.5	1.1	1.11	98.96
NEUT (10^3/µL)	1	10	0.79 - 0.86	0.82	0.023	2.84
	2	10	6.34 - 6.55	6.47	0.072	1.12
	3	10	34.00 - 35.16	34.74	0.369	1.06
NEUT (%)	1	10	44.8 - 47.9	46.4	1.06	2.29
	2	10	56.0 - 58.7	57.1	0.86	1.50
	3	10	80.6 - 82.2	81.5	0.52	0.64
LYMPH (10^3/µL)	1	10	0.36 - 0.45	0.42	0.026	6.18
	2	10	1.78 - 1.98	1.88	0.059	3.15
	3	10	5.37 - 5.86	5.59	0.142	2.54
LYMPH (%)	1	10	8.8 - 9.5	9.1	0.21	2.26
	2	10	17.1 - 20.5	19.3	1.19	6.18
	3	10	29.1 - 32.4	31.0	0.92	2.98

Measurand	Sample	N	Range	Mean	SD	CV %
MONO ($10^3/\mu L$)	1	10	0.03 - 0.04	0.04	0.005	13.06
	2	10	0.60 - 0.68	0.64	0.024	3.68
	3	10	6.27 - 8.30	7.20	0.621	8.63
MONO (%)	1	10	1.2 - 1.5	1.4	0.13	9.40
	2	10	12.0 - 13.8	12.9	0.52	4.04
	3	10	22.2 - 28.3	24.8	1.82	7.32
EO ($10^3/\mu L$)	1	10	0.05 - 0.08	0.06	0.009	14.82
	2	10	0.15 - 0.20	0.17	0.016	9.06
	3	10	0.78 - 0.93	0.83	0.043	5.15
EO (%)	1	10	1.3 - 1.5	1.3	0.07	5.22
	2	10	2.5 - 3.3	2.9	0.25	8.95
	3	10	3.8 - 5.2	4.5	0.46	10.28
BASO ($10^3/\mu L$)	1	10	0.02 - 0.06	0.04	0.011	29.88
	2	10	0.04 - 0.06	0.05	0.008	16.43
	3	10	0.07 - 0.13	0.10	0.019	19.12
BASO (%)	1	10	0.3 - 0.6	0.4	0.13	35.14
	2	10	0.3 - 0.7	0.6	0.16	29.40
	3	10	0.6 - 1.2	1.1	0.16	15.53
IG ($10^3/\mu L$)	1	10	0.03 - 0.07	0.05	0.011	23.65
	2	10	0.12 - 0.20	0.15	0.027	17.71
	3	10	12.21 - 13.62	12.91	0.396	3.07
IG (%)	1	10	0.5 - 1.2	0.8	0.20	23.27
	2	10	1.6 - 2.6	2.0	0.34	16.70
	3	10	19.8 - 22.2	21.0	0.64	3.06
IPF ($10^3/\mu L$)	1	10	1.1 - 1.4	1.3	0.11	8.64
	2	10	5.1 - 6.3	5.8	0.39	6.76
	3	10	14.5 - 17.0	16.0	0.68	4.25
IPF (%)	1	10	0.6 - 0.7	0.6	0.03	5.18
	2	10	5.5 - 6.2	5.9	0.22	3.72
	3	10	13.7 - 16.6	15.5	0.99	6.37
RET (%)	1	10	1.46 - 1.66	1.55	0.070	4.52
	2	10	1.74 - 1.93	1.85	0.062	3.38

Measurand	Sample	N	Range	Mean	SD	CV %
	3	10	2.24 - 2.58	2.42	0.113	4.65
RET (10^6/µL)	1	10	0.0274 - 0.0310	0.0290	0.00117	4.03
	2	10	0.0493 - 0.0568	0.0534	0.00252	4.72
	3	10	0.1119 - 0.1235	0.1184	0.00379	3.20
IRF (%)	1	10	4.7 - 6.8	5.9	0.71	11.96
	2	10	12.9 - 18.5	15.9	1.54	9.65
	3	10	29.0 - 34.8	32.3	2.15	6.65
RET-He (pg)	1	10	30.2 - 31.6	31.0	0.45	1.45
	2	10	34.8 - 35.5	35.2	0.25	0.70
	3	10	39.8 - 40.5	40.2	0.20	0.49

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 measured in replicates of ten in the body fluid mode on the integrated XR-10 and XR-20 analyzers at one internal US site. 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 the integrated analyzers met manufacturer's specifications.

Linearity:

Whole Blood

Linearity studies were performed and testing was conducted at one internal U.S. site. 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). All samples were mixed thoroughly prior to testing in replicates of three in the whole blood mode. Testing and analysis of the data were conducted in accordance with CLSI EP06-ED2:2020. The results from the verification of whole blood linearity for directly measured WBC, RBC, HGB, HCT, PLT-I, PLT-F and RET% parameters on the integrated XR-10 and XR-20 analyzers met the predefined performance criteria.

Parameter	Linear Range
WBC ($x10^3$/µL)	0.03 – 440.00
RBC ($x10^6$/µL)	0.01 – 8.60
HGB (g/dL)	0.1 – 26.0
HCT (%)	0.1 – 75.0

Parameter	Linear Range
PLT(x10^3/µL)	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 at one internal site. Testing and analysis of the data were conducted in accordance with CLSI EP06-ED2:2020. The results of verification of body fluid linearity for measured WBC-BF, RBC-BF and TC-BF parameters on the integrated XR-10 and XR-20 analyzers, confirm the method to be linear from the lower limit to upper limit and are within the measured maximum allowable deviation from linearity for each interval. All results met predefined acceptance criteria.

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

Detection Limit:

Whole Blood Mode

Limits of Blank (LoB), Limit of Detection (LoD), and the Limit of Quantitation (LoQ) were verified for the direct measured WBC, RBC, HGB, HCT and PLT parameters on the integrated XR-10 and XR-20 analyzers. In LoB testing, four blank samples were measured in replicates of five, over a period of three days using two different reagent lots. 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 different reagent lots on a single integrated XR-10 and a single integrated XR-20 analyzer on two separate XR-9000 system configurations.

The results from the verification of whole blood LoB, LoD, and LoQ parameters on the integrated XR-10, and XR-20 analyzers met the predefined performance criteria.

XR-Series	Parameter	LoB	LoD	LoQ
XR-10	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

XR-Series	Parameter	LoB	LoD	LoQ
	PLT-I (x 10^3/µL)	0	1	2
	PLT-F (x 10^3/µL)	0	1	2
XR-20	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 verified for the direct measured WBC-BF, RBC-BF and TC-BF parameters on the integrated XR-10 and XR-20 analyzers. In LoB testing, four blank samples were measured in replicates of five over a period of three days using two different reagent lots. 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 different reagent lots on the integrated analyzers. The study was conducted in accordance with the CLSI EP17- A2 guideline. The results from the verification of body fluid LoB, LoD, and LoQ on the integrated XR-10, and XR-20 analyzers met the predefined performance criteria.

XR Series	Parameter	LoB	LoD	LoQ
XR-10	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
XR-20	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

Carryover:

Whole Blood

Three sets of carryover sequences were run on the integrated XR-10 and XR-20 for each applicable parameter at one internal US clinical site using residual venous whole blood samples collected in K2EDTA 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 the whole blood mode.

The study was conducted in accordance with CLSI H26-A2. The results from the verification of whole blood carryover for directly measured WBC, RBC, HGB, HCT, PLT-I and PLT-F parameters on the integrated XR-10 and XR-20 analyzers met the predefined performance criteria.

Body Fluid

Carryover was conducted using residual peritoneal, pleural and synovial fluids collected in K2EDTA 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 at one internal US clinical site using residual peritoneal, pleural and synovial fluid samples collected in K2EDTA anticoagulant and CSF without anticoagulant. Testing was performed on a single integrated XR-10 and a single integrated XR-20 analyzer. 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 the body fluid mode. The study was conducted in accordance with CLSI H26-A2. The results from the verification of body fluid carryover for directly measured WBC- BF, RBC-BF, and TC-BF parameters on the integrated XR-10 and XR-20 analyzers met the predefined performance criteria.

Comparison Studies:

Whole Blood - Method Comparison

Testing was conducted at one internal U.S. site. A total of 499 de-identified residual K2EDTA venous whole blood samples were utilized. The study included a mix of normal samples (no flags, marked as negative) and abnormal samples (contained flags, marked as positive) with values around medical decision levels and the upper measuring range of directly measured WBC, HGB and PLT parameters. One sample was excluded from the final analysis. Two distinct XR-9000 system configurations were tested; the first utilized a total of two integrated XR-10 analyzers, and the second utilized one integrated XR-20 analyzer. The results of the linear regression analyses and bias analyses from the whole blood method comparison data for all claimed parameters on the integrated XR-10 and XR-20 analyzers met the predefined correlation and coefficient and/or bias performance criteria.

Correlation and Estimated Bias Between XR-9000 (XR-10 Line 1) vs. XR-10 Standalone analyzer – Whole Blood

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC (10^3/µL)	282	0.05 - 176.78	0.9997	1.006 (0.993, 1.019)	0.018 (-0.113, 0.149)	0.10	0.70
RBC (10^6/µL)	282	2.06 - 7.86	0.9991	0.991 (0.986, 0.996)	0.062 (0.043, 0.081)	0.03	0.66
HGB (g/dL)	282	6.0 - 22.4	0.9995	0.982 (0.978, 0.986)	0.230 (0.188, 0.272)	0.0	0.11
HCT (%)	282	19.0 - 67.3	0.9989	0.990 (0.984, 0.995)	0.672 (0.469, 0.874)	0.3	0.81
MCV (fL)	282	72.7 - 113.2	0.9979	1.007 (0.998, 1.016)	-0.527 (-1.365, 0.312)	0.1	0.16
MCH (pg)	282	22.1 - 57.1	0.9884	0.937 (0.852, 1.022)	1.722 (-0.815, 4.260)	-0.2	-0.55
MCHC (g/dL)	282	27.8 - 57.3	0.9742	0.911 (0.740, 1.081)	2.697 (-2.851, 8.244)	-0.2	-0.69
PLT-I (10^3/µL)	281	2 - 2094	0.9992	1.010 (0.999, 1.021)	0.130 (-2.386, 2.645)	3	1.07
PLT-F (10^3/µL)	280	2 - 2434	0.9997	0.995 (0.984, 1.006)	1.605 (-1.186, 4.395)	0	0.05
RDW-SD (fL)	281	37.2 - 103.6	0.9980	1.002 (0.989, 1.014)	0.046 (-0.549, 0.640)	0.1	0.26
RDW-CV (%)	281	11.1 - 29.3	0.9986	1.002 (0.995, 1.008)	-0.027 (-0.119, 0.065)	0.0	0.00
MPV (fL)	255	8.1 - 14.5	0.9445	1.008 (0.953, 1.063)	-0.012 (-0.583, 0.559)	0.1	0.70
NRBC (10^3/µL)	69	0.02 - 0.81	0.9904	0.970 (0.894, 1.046)	-0.003 (-0.008, 0.002)	-0.01	-7.46

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
NRBC (%)	282	0.0 - 28.6	0.9199	0.702 (0.370, 1.034)	0.018 (-0.045, 0.081)	-0.1	-24.22
NEUT (10^3/µL)	281	0.00 - 55.24	0.9971	1.002 (0.972, 1.032)	0.093 (-0.069, 0.255)	0.11	1.38
LYMPH (10^3/µL)	281	0.02 - 116.40	0.9988	1.008 (0.979, 1.037)	-0.093 (-0.162, -0.023)	-0.07	-1.84
MONO (10^3/µL)	281	0.00 - 18.08	0.9174	1.090 (0.621, 1.559)	-0.068 (-0.476, 0.340)	0.02	2.27
EO (10^3/µL)	281	0.00 - 1.48	0.9949	1.011 (0.991, 1.032)	0.004 (0.001, 0.007)	0.01	3.38
BASO (10^3/µL)	281	0.00 - 15.93	0.8906	1.411 (-0.745, 3.568)	-0.009 (-0.212, 0.194)	0.06	35.67
NEUT (%)	281	0.0 - 89.4	0.9946	1.010 (0.991, 1.030)	-0.137 (-1.504, 1.230)	0.5	0.81
LYMPH (%)	281	1.9 - 99.0	0.9948	1.008 (0.993, 1.022)	-0.704 (-1.002, -0.407)	-0.5	-2.60
MONO (%)	281	0.0 - 60.0	0.9825	1.021 (0.947, 1.095)	-0.112 (-0.751, 0.528)	0.1	0.91
EO (%)	281	0.0 - 18.5	0.9677	1.021 (0.981, 1.060)	0.002 (-0.078, 0.083)	0.0	2.18
BASO (%)	281	0.0 - 9.4	0.7882	1.184 (0.749, 1.620)	-0.080 (-0.340, 0.180)	0.1	8.36
IG (10^3/µL)	281	0.00 - 77.63	0.9998	0.987 (0.969, 1.004)	-0.020 (-0.035, -0.006)	-0.04	-3.13
IG (%)	281	0.0 - 47.5	0.9779	0.979 (0.956, 1.002)	-0.098 (-0.220, 0.023)	-0.2	-5.20
RET (%)	282	0.07 - 17.35	0.9974	0.984 (0.956, 1.012)	0.073 (0.020, 0.127)	0.04	1.88

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
RET (10^6/µL)	261	0.0120 - 0.5141	0.9961	0.994 (0.974, 1.014)	0.003 (0.001, 0.004)	0.0022	2.63
IRF (%)	282	0.0 - 52.6	0.9628	1.003 (0.964, 1.042)	0.884 (0.352, 1.415)	0.9	6.38
RET-He (pg)	281	17.6 - 46.2	0.9857	1.025 (1.007, 1.044)	0.088 (-0.497, 0.674)	0.9	2.79
IPF (%)	282	0.3 - 35.1	0.9941	1.038 (0.984, 1.092)	-0.036 (-0.208, 0.136)	0.1	2.82
IPF (10^3/µL)	277	0.4 - 138.7	0.9981	0.996 (0.927, 1.064)	0.280 (-0.187, 0.747)	0.2	3.12

Correlation and Estimated Bias Between XR-9000 (XR-10 Line 2) vs. XR-10 Standalone analyzer – Whole Blood

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC (10^3/µL)	282	0.05 - 176.78	0.9999	0.993 (0.986, 1.000)	-0.026 (-0.106, 0.054)	-0.12	-0.86
RBC (10^6/µL)	282	2.06 - 7.86	0.9988	1.014 (1.007, 1.020)	-0.028 (-0.053, -0.003)	0.03	0.69
HGB (g/dL)	282	6.0 - 22.4	0.9995	0.993 (0.989, 0.997)	0.103 (0.058, 0.149)	0.0	0.18
HCT (%)	282	19.0 - 67.3	0.9986	1.010 (1.003, 1.017)	0.005 (-0.245, 0.255)	0.4	1.03
MCV (fL)	282	72.7 - 113.2	0.9973	1.018 (1.007, 1.028)	-1.240 (-2.222, -0.258)	0.4	0.41
MCH (pg)	282	22.1 - 57.1	0.9820	0.919 (0.803, 1.035)	2.322 (-1.142, 5.786)	-0.1	-0.43
MCHC (g/dL)	282	27.8 - 57.3	0.9612	0.872 (0.644, 1.101)	3.912 (-3.527, 11.352)	-0.3	-0.81
PLT-I (10^3/µL)	281	2 - 2094	0.9993	0.998 (0.990, 1.005)	0.080 (-1.453, 1.612)	-1	-0.22
PLT-F (10^3/µL)	280	2 - 2434	0.9996	0.988 (0.979, 0.997)	1.361 (-0.801, 3.523)	-2	-0.71
RDW-SD (fL)	281	37.2 - 103.6	0.9979	1.015 (1.002, 1.027)	0.027 (-0.600, 0.654)	0.8	1.54
RDW-CV (%)	281	11.1 - 29.3	0.9980	0.995 (0.986, 1.004)	0.214 (0.087, 0.342)	0.1	0.89
MPV (fL)	254	8.1 - 14.5	0.9474	1.015 (0.956, 1.074)	-0.048 (-0.646, 0.551)	0.1	1.08
NRBC (10^3/µL)	69	0.02 - 0.81	0.9872	0.972 (0.867, 1.077)	-0.003 (-0.009, 0.003)	0.00	-6.65

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
NRBC (%)	282	0.0 - 28.6	0.8446	0.401 (0.268, 0.534)	0.063 (0.031, 0.094)	-0.1	-40.07
NEUT (10^3/µL)	281	0.00 - 55.24	0.9975	0.995 (0.963, 1.027)	-0.002 (-0.188, 0.184)	-0.04	-0.49
LYMPH (10^3/µL)	281	0.02 - 116.40	0.9995	1.005 (1.002, 1.008)	0.018 (-0.023, 0.059)	0.04	1.00
MONO (10^3/µL)	281	0.00 - 18.08	0.9541	0.972 (0.803, 1.140)	-0.013 (-0.157, 0.131)	-0.04	-4.12
EO (10^3/µL)	281	0.00 - 1.48	0.9936	0.991 (0.971, 1.010)	0.004 (0.001, 0.007)	0.00	1.21
BASO (10^3/µL)	281	0.00 - 15.93	0.8738	1.052 (-0.660, 2.764)	0.013 (-0.151, 0.177)	0.02	12.73
NEUT (%)	281	0.0 - 89.4	0.9951	1.015 (1.002, 1.029)	-0.611 (-1.524, 0.302)	0.4	0.56
LYMPH (%)	281	1.9 - 99.0	0.9876	1.020 (1.005, 1.035)	-0.020 (-0.402, 0.363)	0.4	1.91
MONO (%)	281	0.0 - 60.0	0.9328	0.922 (0.832, 1.012)	0.511 (-0.170, 1.191)	-0.2	-2.29
EO (%)	281	0.0 - 18.5	0.9718	1.009 (0.960, 1.059)	0.014 (-0.087, 0.114)	0.0	1.59
BASO (%)	281	0.0 - 9.4	0.8961	1.041 (0.779, 1.303)	0.002 (-0.150, 0.154)	0.0	4.33
IG (10^3/µL)	281	0.00 - 77.63	0.9995	0.973 (0.948, 0.999)	-0.069 (-0.092, -0.045)	-0.10	-8.81
IG (%)	281	0.0 - 47.5	0.9595	0.945 (0.894, 0.996)	-0.440 (-0.610, -0.270)	-0.6	-19.38
RET (%)	282	0.07 - 17.35	0.9972	0.999 (0.978, 1.020)	0.073 (0.033, 0.113)	0.07	3.38

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
RET (10^6/µL)	261	0.0120 - 0.5141	0.9957	1.015 (0.991, 1.040)	0.002 (0.000, 0.004)	0.0036	4.31
IRF (%)	282	0.0 - 52.6	0.9678	1.001 (0.971, 1.030)	0.017 (-0.447, 0.482)	0.0	0.18
RET-He (pg)	281	17.6 - 46.2	0.9880	1.014 (0.997, 1.032)	-0.185 (-0.754, 0.384)	0.3	0.86
IPF (%)	282	0.3 - 35.1	0.9910	1.032 (0.988, 1.076)	-0.038 (-0.178, 0.103)	0.1	2.23
IPF (10^3/µL)	277	0.4 - 138.7	0.9947	0.986 (0.929, 1.043)	0.185 (-0.213, 0.584)	0.1	0.97

Correlation and Estimated Bias Between XR-9000 (XR-20 Line) vs. XR-20 Standalone analyzer – Whole Blood

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC (10^3/µL)	216	0.15 - 276.14	0.9998	0.979 (0.944, 1.014)	0.154 (-0.221, 0.529)	-0.12	-0.92
RBC (10^6/µL)	216	1.91 - 6.12	0.9978	0.990 (0.977, 1.003)	0.062 (0.008, 0.117)	0.02	0.59
HGB (g/dL)	216	5.0 - 19.0	0.9994	0.995 (0.991, 1.000)	0.147 (0.091, 0.204)	0.1	0.78
HCT (%)	216	15.4 - 55.1	0.9972	0.990 (0.976, 1.004)	0.709 (0.163, 1.256)	0.4	1.01
MCV (fL)	216	69.3 - 106.3	0.9969	1.013 (1.004, 1.022)	-0.740 (-1.557, 0.078)	0.4	0.43
MCH (pg)	216	22.1 - 69.7	0.9714	0.835 (0.542, 1.127)	5.064 (-3.753, 13.880)	0.0	0.03
MCHC (g/dL)	216	29.5 - 72.5	0.9615	0.705 (0.260, 1.149)	9.877 (-5.074, 24.828)	-0.1	-0.39
PLT-I (10^3/µL)	216	19 - 1084	0.9971	1.016 (0.986, 1.046)	-4.435 (-11.425, 2.555)	0	-0.03
PLT-F (10^3/µL)	216	19 - 1074	0.9984	0.998 (0.974, 1.022)	-0.502 (-6.521, 5.517)	-1	-0.38
RDW-SD (fL)	216	35.5 - 99.6	0.9981	1.004 (0.994, 1.014)	0.394 (-0.066, 0.854)	0.6	1.20
RDW-CV (%)	216	11.3 - 29.2	0.9987	0.998 (0.990, 1.006)	0.201 (0.084, 0.317)	0.2	1.14
MPV (fL)	210	7.8 - 13.6	0.9698	0.980 (0.947, 1.014)	0.336 (0.009, 0.663)	0.1	1.35
NRBC (10^3/µL)	33	0.02 - 1.54	0.9985	1.217 (0.812, 1.622)	-0.010 (-0.029, 0.009)	0.01	10.74

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
NRBC (%)	216	0.0 - 1.0	0.3357	4.670 (-4.250, 13.590)	-0.116 (-0.380, 0.149)	0.0	50.63
NEUT (10^3/µL)	216	0.00 - 125.19	0.9994	1.018 (0.975, 1.060)	-0.139 (-0.427, 0.149)	0.00	0.05
LYMPH (10^3/µL)	216	0.02 - 17.35	0.9943	1.019 (0.989, 1.048)	-0.039 (-0.077, -0.002)	-0.01	-0.32
MONO (10^3/µL)	216	0.00 - 8.28	0.9796	0.997 (0.909, 1.086)	-0.013 (-0.077, 0.051)	-0.02	-1.46
EO (10^3/µL)	216	0.00 - 7.22	0.9985	0.957 (0.878, 1.037)	0.011 (-0.008, 0.031)	0.00	-0.50
BASO (10^3/µL)	216	0.00 - 11.69	0.9998	0.883 (0.854, 0.913)	0.004 (0.001, 0.006)	-0.01	-8.27
NEUT (%)	216	0.0 - 91.5	0.9858	0.995 (0.946, 1.044)	0.771 (-2.458, 4.000)	0.5	0.75
LYMPH (%)	216	2.4 - 100.0	0.9921	0.961 (0.892, 1.030)	0.766 (-0.610, 2.142)	-0.1	-0.49
MONO (%)	216	0.0 - 26.7	0.9667	0.992 (0.938, 1.047)	0.080 (-0.483, 0.643)	0.0	0.02
EO (%)	216	0.0 - 19.7	0.9919	1.001 (0.977, 1.026)	0.056 (-0.013, 0.125)	0.1	1.98
BASO (%)	216	0.0 - 5.4	0.9343	0.858 (0.733, 0.982)	0.070 (-0.006, 0.147)	0.0	-4.49
IG (10^3/µL)	216	0.00 - 107.15	0.9983	0.890 (0.663, 1.116)	0.065 (-0.132, 0.263)	-0.09	-6.45
IG (%)	216	0.0 - 38.8	0.9452	1.038 (0.918, 1.158)	-0.490 (-0.709, -0.271)	-0.4	-11.95
RET (%)	216	0.15 - 11.39	0.9971	1.045 (1.025, 1.065)	-0.044 (-0.081, -0.007)	0.05	2.26

Measurand	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
RET (10^6/µL)	212	0.0125 - 0.3576	0.9952	1.045 (1.025, 1.065)	-0.001 (-0.003, 0.000)	0.0020	2.70
IRF (%)	216	0.0 - 44.5	0.9713	1.008 (0.976, 1.041)	0.964 (0.560, 1.369)	1.1	8.00
RET-He (pg)	216	15.3 - 42.1	0.9939	1.022 (1.003, 1.042)	-0.440 (-1.073, 0.194)	0.3	0.86
IPF (%)	216	0.3 - 14.3	0.9893	1.167 (1.119, 1.214)	0.258 (0.156, 0.361)	0.7	26.74
IPF (10^3/µL)	216	0.7 - 24.0	0.9881	1.215 (1.164, 1.267)	0.379 (0.124, 0.633)	1.7	27.49

Body Fluid - Method Comparison

Testing was conducted at one internal U.S. site. A total of 209 (37 CSF, 62 pleural, 71 peritoneal and 39 synovial) de-identified residual body fluid samples were utilized. The study included a mix of normal and abnormal samples with values targeting the full analytical measurement range of directly measured WBC-BF and RBC-BF parameters. Three samples were excluded from the final analysis. All body fluids were collected in K2EDTA anticoagulant, with the exception of CSF. Two distinct XR-9000 system configurations were tested; the first utilized a total of two integrated XR-10 analyzers, and the second utilized one integrated XR-20 analyzer. All samples were premixed by gentle hand inversion, run in singlet using the body fluid mode**,** and within two hours on each analyzer. The results of the linear regression analyses and bias analyses from all combined body fluids for all claimed parameters on the integrated XR-10 and XR-20 analyzers met the predefined correlation and coefficient and/or bias performance criteria for method comparison.

Correlation and Estimated Bias Between XR-9000 (XR-10 Line 1) vs. XR-10 Standalone analyzer – All Combined Body Fluids

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC-BF (10^3/µL)	111	0.003 - 9.403	0.9983	1.015 (0.989, 1.040)	-0.004 (-0.019, 0.011)	0.012	1.11
RBC-BF (10^6/µL)	62	0.002 - 4.748	0.9988	0.993 (0.973, 1.014)	-0.006 (-0.016, 0.004)	-0.009	-1.95
TC-BF (10^3/µL)	112	0.003 - 9.407	0.9983	1.012 (0.986, 1.039)	-0.007 (-0.023, 0.010)	0.007	0.59
MN (10^3/µL)	115	0.003 - 3.171	0.9862	0.987 (0.908, 1.066)	-0.014 (-0.039, 0.010)	-0.020	-4.49
PMN (10^3/µL)	108	0.003 - 9.770	0.9981	1.072 (1.032, 1.112)	-0.013 (-0.033, 0.007)	0.056	5.80
MN (%)	123	0.0 - 100.0	0.9162	1.044 (0.998, 1.090)	-1.210 (-3.971, 1.550)	1.2	2.22
PMN (%)	123	0.0 - 100.0	0.9162	1.044 (0.998, 1.090)	-3.171 (-6.753, 0.411)	-1.2	-2.82

Correlation and Estimated Bias Between XR-9000 (XR-10 Line 2) vs. XR-10 Standalone analyzer – All Combined Body Fluids

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC-BF (10^3/µL)	111	0.003 - 9.403	0.9981	1.044 (1.019, 1.068)	-0.019 (-0.035, -0.004)	0.028	2.62
RBC-BF (10^6/µL)	61	0.002 - 4.748	0.9988	0.989 (0.970, 1.008)	-0.006 (-0.017, 0.004)	-0.012	-2.51
TC-BF (10^3/µL)	112	0.003 - 9.407	0.9981	1.042 (1.017, 1.067)	-0.020 (-0.036, -0.004)	0.027	2.39
MN (10^3/µL)	115	0.003 - 3.171	0.9817	0.986 (0.900, 1.072)	-0.006 (-0.027, 0.014)	-0.013	-2.76
PMN (10^3/µL)	108	0.003 - 9.770	0.9978	1.099 (1.063, 1.135)	-0.022 (-0.037, -0.006)	0.074	7.66
MN (%)	123	0.0 - 100.0	0.9024	1.015 (0.963, 1.067)	1.040 (-2.796, 4.877)	1.9	3.38
PMN (%)	123	0.0 - 100.0	0.9024	1.015 (0.963, 1.067)	-2.558 (-5.840, 0.724)	-1.9	-4.30

Correlation and Estimated Bias Between XR-9000 (XR-20 Line) vs. XR-20 Standalone analyzer – All Combined Body Fluids

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)	Mean Diff.	Mean %Diff.
WBC-BF (10^3/µL)	81	0.003 - 9.881	0.9971	0.988 (0.957, 1.020)	-0.064 (-0.118, -0.010)	-0.095	-3.54
RBC-BF (10^6/µL)	56	0.002 - 4.727	0.9998	1.002 (0.996, 1.008)	0.001 (-0.003, 0.005)	0.004	0.27
TC-BF (10^3/µL)	81	0.003 - 9.968	0.9973	0.987 (0.956, 1.018)	-0.073 (-0.127, -0.020)	-0.108	-3.98
MN (10^3/µL)	79	0.003 - 3.186	0.9903	0.869 (0.817, 0.922)	-0.000 (-0.026, 0.026)	-0.104	-13.07
PMN (10^3/µL)	78	0.003 - 8.249	0.9944	1.019 (0.972, 1.066)	-0.030 (-0.080, 0.020)	0.007	0.37
MN (%)	82	6.4 - 100.0	0.9788	1.064 (1.012, 1.116)	-4.611 (-6.878, -2.343)	-1.6	-3.26
PMN (%)	82	0.0 - 93.6	0.9788	1.064 (1.012, 1.116)	-1.805 (-5.227, 1.617)	1.6	2.97

Verification of SP-50 Functionality:

Testing was conducted at one internal U.S. site utilizing one SP-50 Automated Hematology Slide Preparation Unit integrated with one XR-10 and one XR-20 analyzer within the XR-9000 system configuration. A total of 61 specimens were used. The data from the automated workflow evaluation confirms that the integrated SP-50 maintained the performance characteristics of its predicate standalone analyzers.

Conclusions:

The integrated SP-50 Automated Slide Preparation Unit within the XR-9000 system configuration and the predicate standalone devices, XR-10 (K250943) and XR-20 (K251371) Automated Hematology analyzers, have similar indications for use, fundamental technology, and principles of operation.

Performance verification testing were conducted to characterize the performance of the integrated XR-10 and XR-20 analyzers within the XR-Series XR-9000 system configuration using predetermined acceptance criteria. Results of this testing demonstrated that the integrated XR-10 and XR-20 analyzers are substantially equivalent to the standalone XR-10 (K250943) and standalone XR-20 (K251371) Automated Hematology analyzers.