510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K253212

B Applicant

Sysmex America, Inc.

C Proprietary and Established Names

XR-Series System Configuration

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	II	864.5220	Hematology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of new device configurations

B Measurand:

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

Body Fluid: WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#

C Type of Test:

Quantitative test for complete blood counts (CBC) with 6-part blood cell differential, nucleated red blood cells counts, reticulocyte analysis and body fluid counts.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The Sysmex XR-Series System Configurations 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 XR-Series system configurations are comprised of the previously cleared XR-Series analyzers (XR-10 and XR-20), and the 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.

B Principle of Operation:

The XR-Series System Configurations 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.

C Instrument Description Information:

1. Instrument Name:

   XR-Series System Configurations

2. Specimen Identification:

   Specimen identification can be performed manually by an operator or barcode labels can be affixed to the sample tubes and racks to enable automatic reading of the ID by barcode reader.

3. Specimen Sampling and Handling:

The XR-Series System Configurations uses the same sample modes as cleared in the Sysmex XR-Series (XR-10) Automated Hematology Analyzer (K250943) and Sysmex XR-Series (XR-20) Automated Hematology Analyzer (K251371):

- Whole Blood mode
- Pre-Dilution mode
- Low WBC Mode
- Body fluid Analysis Mode

4. Calibration:

The XR-Series System Configurations uses the same calibrators as cleared in the Sysmex XR-Series (XR-10) Automated Hematology Analyzer (K250943) and Sysmex XR-Series (XR-20) Automated Hematology Analyzer (K251371):

- XN CAL: Use for the calibration of the analyzer for WBC, RBC, HGB, HCT, PLT, and RET
- XN CAL PF: Use for the calibration of the analyzer for PLT-F (platelet count analyzed by the PLT-F channel).

5. Quality Control:

The XR-Series System Configurations (uses the same commercial controls as cleared in the Sysmex XR-Series (XR-10) Automated Hematology Analyzer (K250943) and Sysmex XR-Series (XR-20) Automated Hematology Analyzer (K251371):

- XN CHECK: is a trilevel control for whole blood used to monitor the performance of the XR analyzer.
- XN CHECK BF: is a bi-level control for body fluid

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Sysmex XR-Series (XR-10) Automated Hematology Analyzer
Sysmex XR-Series (XR-20) Automated Hematology Analyzer

B Predicate 510(k) Number(s):

K250943
K251371

C Comparison with Predicate(s):

Device & Predicate Device(s):	K2532125	K250943 & K251371
Device Trade Name	XR-Series System Configuration	Sysmex XR-Series (XR-10) Automated Hematology Analyzer & Sysmex XR-Series (XR-20) Automated Hematology Analyzer
General Device Characteristic Similarities		
Intended Use/Indications for Use	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-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%/#,	K250943: 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

	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.	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. K251371: The XR-Series module (XR-20) is a quantitative multi parameter automated hematology analyzer intended for in vitro The XN-Series modules (XN-10, XN-20) are quantitative multi parameter automated hematology analyzers intended for in vitro K251371 - Page 4 of 32 K251371 - Page 5 of 32 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%/#, YMPH%/#, 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 or synovial fluids in K2EDTA anticoagulant) and CSF	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%/#,	Same

	RET%/#, IRF, IPF, IPF#1, RET-He Body Fluid Mode: WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	
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
Throughput	Pre-Dilution mode: Approximately 90 samples/hour Body Fluid: 40 samples/hour maximum	Same
Controls/ Calibrator	XN CAL (Calibrator) XN CAL PF (Calibrator) XN CHECK (Quality control) XN CHECK BF (Quality Control)	Same
Analysis Modes	Whole Blood Mode Low WBC Mode Pre-dilution Mode	Same

	Body Fluid Mode RBT Analysis Microanalysis Manual Analysis	
Sample Aspiration/ Fluidic Pathway	Single Pathway	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
General Device Characteristic Differences		
System Configurations	An integrated system that connects the XR-10 and XR-20 analyzers with the SP-50 Automated Hematology Slide Preparation Unit and sample transport system via hardware and software integration	Standalone analyzer
Workstation	The system (up to nine XR-series analyzers plus one SP-50) is managed by a single central Information Processing Unit (IPU)	Standalone analyzer managed by its own dedicated information processing unit (IPU)
SP-50 Slide Preparation Unit	The SP-50 Slide Preparation Uni 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 slide and staining the smear.	Not applicable

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.
- CLSI EP06-2nd Edition, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach. Approved Guideline.
- CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard– Second Edition
- CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition.
- CLSI EP09c 3rd Edition, Measurement Procedure Comparison and Bias estimation using Patient Samples
- ANSI AAI ISO 14971:2019 medical devices – Application of risk management to medical devices
- AAMI TIR57:2016 Principles for Medical device security – Risk Management
- ANSI AAMI SW96:2023 Standard for Medical device security – Security risk management for device manufacturers

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Testing was conducted in accordance with the CLSI EP05-A3 Guideline.

Whole Blood Repeatability
Testing was performed on two different XR-9000 configurations at one internal U.S. site by two operators where samples were tested in ten replicates. The study was conducted using residual K2EDTA whole blood samples to target specific concentration ranges for each parameter targeting medical decision levels, normal, and high measurement range of WBC, HGB and PLT parameters and the low, normal, and high measurement ranges of RBC and HCT parameters. The mean, standard deviation (SD), and coefficient of variation (%CV) were calculated for each parameter. All samples met acceptance criteria requirements, and the results are summarized below.

Whole Blood Repeatability – XR-9000 Configuration with XR-10 (K250943)

Parameter (units)	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

Parameter (units)	Sample	N	Range	Mean	SD	CV %
	High	10	92.37 - 93.61	92.89	0.0407	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
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

Parameter (units)	Sample	N	Range	Mean	SD	CV %
	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
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

Parameter (units)	Sample	N	Range	Mean	SD	CV %
	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
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/µL)	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/µL)	1	10	0.06 - 0.11	0.08	0.015	20.12
	2	10	0.09 - 0.15	0.12	0.018	15.47

Parameter (units)	Sample	N	Range	Mean	SD	CV %
	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/µL)	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/µL)	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
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

Whole Blood Repeatability – XR-9000 Configuration with XR-20 (K251371)

Measurand	Sample	N	Range	Mean	SD	CV %
WBC (10^3/µL)	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/µL)	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	37.4	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
PLT-I (10^3/µL)	MDL	10	8 - 10	9	0.7	8.11
	Normal	10	211 - 222	215	3.6	1.70
	High	10	587 - 616	604	7.9	1.31

Measurand	Sample	N	Range	Mean	SD	CV %
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

Measurand	Sample	N	Range	Mean	SD	CV %
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
MONO (10^3/µL)	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/µL)	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/µL)	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

Measurand	Sample	N	Range	Mean	SD	CV %
IG (10^3/µL)	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/µL)	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
	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

Body Fluids Repeatability

Testing was performed on two different XR-9000 configurations at one internal U.S. site by two operators where samples were tested in ten replicates. The study was conducted using Residual peritoneal, pleural, and synovial fluid samples collected in K2EDTA and CSF samples without anticoagulant to target low and high concentration ranges for directly measured parameter were tested in replicates of ten. The mean, SD, and %CV were calculated for each parameter. All samples met acceptance criteria requirements, and the results are summarized below.

Body Fluid Repeatability XR- 9000 Configuration – XR- 10

Type	Parameter	Level	N	Range	Mean	SD	CV%
CSF	WBC-BF ($10^3/\mu L$)	Low	10	0.002-0.004	0.003	0.0008	24.65
		High	10	6.364-6.594	6.507	0.0792	1.22
	RBC-BF ($10^6/\mu L$)	high	10	3.615-3.682	3.646	0.0187	0.51
		High	10	4.801-4.884	4.852	0.0236	0.49
	TC-BF ($10^3/\mu L$)	Low	10	0.002-0.004	0.003	0.0008	24.65
		High	10	6.367-6.599	6.514	0.0812	1.25
	MN ($10^3/\mu L$)	Low	10	0.002-0.004	0.003	0.0009	30.19
		High	10	1.358-1.461	1.409	0.0359	2.54
	PMN ($10^3/\mu L$)	Low	10	0.189-0.213	0.202	0.0075	3.73
		High	10	4.980-5.212	5.097	0.0676	1.33
	MN (%)	Low	10	20.9-22.4	21.6	0.48	2.22
		High	10	66.6-100.0	90.8	14.96	16.47
	PMN (%)	Low	10	66.8-73.7	70.0	2.36	3.37
		High	10	77.6-79.1	78.4	0.48	0.61
Peritoneal	WBC-BF ($10^3/\mu L$)	Low	10	0.047-0.058	0.052	0.0035	6.69
		High	10	3.617-3.678	3.639	0.0199	0.55
	RBC-BF ($10^6/\mu L$)	Low	10	0.042-0.045	0.044	0.0009	2.17
		High	10	4.087-4.143	4.107	0.0169	0.41
		Low	10	0.050-0.061	0.056	0.0035	6.36

Type	Parameter	Level	N	Range	Mean	SD	CV%
	TC-BF ($10^3/\mu L$)	High	10	3.949-4.123	4.045	0.0521	1.29
	MN ($10^3/\mu L$)	Low	10	0.033-0.042	0.038	0.0028	7.47
		High	10	0.924-1.073	0.967	0.0433	4.48
	PMN ($10^3/\mu L$)	Low	10	0.003-0.007	0.004	0.0015	34.75
		High	10	3.078-3.214	3.156	0.0427	1.35
	MN (%)	Low	10	21.5-22.3	21.9	0.25	1.15
		High	10	67.4-76.9	73.0	2.52	3.46
	PMN (%)	Low	10	20.5-30.3	24.2	3.21	13.25
		High	10	60.0-100.0	84.1	13.98	16.63
Pleural	WBC-BF ($10^3/\mu L$)	Low	10	0.005-0.007	0.006	0.0007	11.84
		High	10	6.150-7.052	6.813	0.2560	3.76
	RBC-BF ($10^6/\mu L$)	Low	10	0.007-0.011	0.010	0.0014	14.25
		High	10	4.128-4.200	4.160	0.0247	0.59
	TC-BF ($10^3/\mu L$)	Low	10	0.005-0.007	0.006	0.0008	13.60
		High	10	6.473-7.408	7.161	0.2671	3.73
	MN ($10^3/\mu L$)	Low	10	0.003-0.005	0.004	0.0006	15.06
		High	10	1.791-2.644	2.253	0.2598	11.53
	PMN ($10^3/\mu L$)	Low	10	0.041-0.048	0.044	0.0023	5.14
		High	10	5.150-5.226	5.188	0.0242	0.47
	MN (%) MN (%)	Low	10	6.8-8.8	7.9	0.65	8.27
		High	10	87.3-89.6	88.7	0.82	0.92
	PMN (%)	Low	10	10.4-12.7	11.3	0.82	7.23
		High	10	91.2-93.2	92.1	0.65	0.71
		Low	10	0.003-0.005	0.004	0.0008	22.25

Type	Parameter	Level	N	Range	Mean	SD	CV%
Synovial	WBC-BF (10^3/µL)	High	10	8.406-8.935	8.614	0.140	1.63
	RBC-BF (10^6/µL)	Low	10	0.057-0.060	0.059	0.0008	1.45
		High	10	3.523-3.650	3.585	0.0366	1.02
	TC-BF (10^3/µL)	Low	10	0.003-0.005	0.004	0.0008	22.25
		High	10	8.409-8.938	8.618	0.1401	1.63
	MN (10^3/µL)	Low	10	0.314-0.439	0.360	0.0370	10.29
		High	10	2.185-2.364	2.294	0.0665	2.90
	PMN (10^3/µL)	Low	10	0.002-0.005	0.003	0.0010	28.41
		High	10	8.049-8.579	8.254	0.1380	1.67
	MN (%)	Low	10	3.7-5.1	4.2	0.41	9.82
		High	10	12.2-13.3	12.9	0.38	2.95
	PMN (%)	Low	10	86.7-87.8	87.1	0.38	0.44
		High	10	94.9-96.3	95.8	0.41	0.43

Body Fluid Repeatability XR- 9000 Configuration – XR-20

Type	Parameter	Level	N	Range	Mean	SD	CV%
CSF	WBC-BF (10^3/µL)	Low	10	0.002-0.005	0.004	0.0011	28.63
		High	10	5.059-5.207	5.135	0.0459	0.89
	RBC-BF (10^6/µL)	Low	10	0.007-0.009	0.008	0.0007	9.20
		High	10	4.343-4.394	4.370	0.0160	0.37
	TC-BF (10^3/µL)	Low	10	0.003-0.006	0.004	0.0010	24.59
		High	10	5.060-5.209	5.137	0.0461	0.90
	MN (10^3/µL)	Low	10	0.001-0.004	0.003	0.0010	38.87
		High	10	1.639-1.733	1.672	0.0255	1.53
	PMN (10^3/µL)	Low	10	0.002-0.011	0.005	0.0029	56.57

Type	Parameter	Level	N	Range	Mean	SD	CV%
		High	10	3.326-3.542	3.463	0.0617	1.78
	MN (%)	Low	10	12.5-37.5	22.0	8.16	37.17
		High	10	25.0-100.0	68.7	22.34	32.54
	PMN (%)	Low	10	65.7-68.0	67.4	0.70	1.04
		High	10	74.0-77.5	76.2	1.24	1.62
Peritoneal	WBC-BF (10^3/µL)	Low	10	0.029-0.037	0.034	0.0024	7.04
		High	10	8.626-9.076	8.908	0.1216	1.37
	RBC-BF (10^6/µL)	Low	10	0.029-0.031	0.030	0.0008	2.65
		High	10	3.845-3.921	3.889	0.0300	0.77
	TC-BF (10^3/µL)	Low	10	0.003-0.006	0.004	0.0010	25.50
		High	10	8.632-9.085	8.916	0.1223	1.37
	MN (10^3/µL)	Low	10	0.023-0.030	0.027	0.0023	8.76
		High	10	1.688-1.732	1.703	0.0160	0.94
	PMN (10^3/µL)	Low	10	0.004-0.009	0.007	0.0013	19.36
		High	10	7.861-8.310	8.164	0.1256	1.54
	MN (%)	Low	10	7.4-8.9	8.3	0.55	6.64
		High	10	73.5-87.9	79.7	3.79	4.75
	PMN (%)	Low	10	12.1-26.5	20.3	3.79	18.71
		High	10	91.1-92.6	91.7	0.55	0.60
Pleural	WBC-BF (10^3/µL)	Low	10	0.008-0.012	0.010	0.0014	14.14
		High	10	4.208-4.802	4.565	0.2096	4.59
	RBC-BF (10^6/µL)	Low	10	0.006-0.007	0.007	0.0005	8.11
		High	10	3.248-3.312	3.281	0.0237	0.72
	TC-BF (10^3/µL)	Low	10	0.008-0.013	0.010	0.0015	14.51

Type	Parameter	Level	N	Range	Mean	SD	CV%
		High	10	4.597-5.267	5.010	0.2255	4.50
	MN ($10^3/\mu L$)	Low	10	0.006-0.010	0.008	0.0012	15.59
		High	10	2.273-2.407	2.358	0.0391	1.66
	PMN ($10^3/\mu L$)	Low	10	0.270-0.296	0.287	0.0074	2.58
		High	10	2.308-2.844	2.597	0.1724	6.64
	MN (%)	Low	10	10.9-16.1	13.1	1.66	12.65
		High	10	72.8-90.9	80.0	5.72	7.15
	PMN (%)	Low	10	26.8-28.6	28.0	0.54	1.92
		High	10	83.9-89.1	86.9	1.66	1.91
Synovial	WBC-BF ($10^3/\mu L$)	Low	10	0.002-0.003	0.003	0.0005	17.89
		High	10	4.517-4.817	4.684	0.1045	2.23
	RBC-BF ($10^6/\mu L$)	Low	10	0.003-0.005	0.004	0.0006	16.64
		High	10	3.763-3.855	3.821	0.0280	0.73
	TC-BF ($10^3/\mu L$)	Low	10	0.002-0.003	0.003	0.0005	17.89
		High	10	4.517-4.818	4.684	0.1048	2.24
	MN ($10^3/\mu L$)	Low	10	0.024-0.031	0.028	0.0020	7.32
		High	10	1.541-4.284	2.492	1.0180	40.86
	PMN ($10^3/\mu L$)	Low	10	0.001-0.006	0.004	0.0015	37.17
		High	10	3.077-3.302	3.219	0.0771	2.39
	MN (%)	Low	10	1.9-5.1	3.0	1.22	40.27
		High	10	70.3-84.5	78.1	4.46	5.71
	PMN (%)	Low	10	15.5-29.7	21.9	4.46	20.39
		High	10	94.9-98.1	97.0	1.22	1.26

2. Linearity:

Testing was conducted in accordance with CLSI EP06 2nd Edition guideline.

Whole Blood
Linearity studies were performed to validate the linear range of the Sysmex XR-Series System Configurations using the XR-9000 as the representative configuration. A minimum of seven sample dilutions were prepared with concentrations which span the full measurement range, including one level below and one level above the claimed linearity range. Testing was performed in triplicate in the whole blood mode on two different XR-9000 configurations at one internal site. 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 (x10³/µL)	0.03–440.00
RBC (x10⁶/µL)	0.01–8.6
HGB (g/dL)	0.1– 26.0
HCT (%)	0.1–75.0
PLT-I (x10³/µL)	0–5599
PLT-F (x10³/µL)	2–5000
RET (%)	0.00–30.000

Body fluids
Linearity studies were performed to validate the linear range of the Sysmex XR-Series System Configurations using the XR-9000 as the representative configuration. A minimum of seven sample dilutions were prepared with concentrations which span the full measurement range, including one level below and one level above the claimed linearity range. Testing was performed in triplicate in the whole blood mode on two different XR-9000 configurations at one internal site. The results from the verification of whole blood linearity 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.

Parameter	Linear Range
WBC-BF (x10³/µL)	0.003–10.000
RBC-BF (x10⁶/µL)	0.002–5.000
TC-BF (x10³/µL)	0.003–10.000

3. Analytical Specificity/Interference:

Refer to Decision Summaries for K250943 and K251371.

4. Detection Limit and Assay Reportable Range:

Testing was conducted by a minimum of two operators at one internal site in accordance with the CLSI EP17-A2 guideline.

Whole Blood
Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined for WBC, RBC, HGB, HCT, PLT-I and PLT-F parameters in the whole blood mode on a representative configuration. For LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots on a XR-10 and a XR-20 analyzer in the XR-9000 Configuration. For LoD and LoQ testing, four low concentration samples were first analyzed on the Sysmex XN-20 automated hematology analyzer (K112605) to establish reference values. These low-level samples were then measured in five replicates over three days using two reagent lots on a XR-10 and a XR-20 analyzer in the XR-9000 Configuration.

Whole Blood Detection Limits – XR-9000 Configuration (XR-10)

Parameter (units)	LoB	LoD	LoQ
WBC ($10^3/\mu L$)	0.00	0.01	0.02
RBC ($10^6/\mu L$)	0.00	0.01	0.01
HGB (g/dL)	0.0	0.1	0.1
HCT (%)	0.0	0.1	0.1
PLT-I ($10^3/\mu L$)	0	1	2
PLT-F ($10^3/\mu L$)	0	1	2

Whole Blood Detection Limits – XR-9000 Configuration (XR-20)

Parameter (Units)	LoB	LoD	LoQ
WBC ($10^3/\mu L$)	0.00	0.01	0.02
RBC ($10^6/\mu L$)	0.00	0.01	0.01
HGB (g/dL)	0.0	0.1	0.1
HCT (%)	0.0	0.1	0.1
PLT-I ($10^3/\mu L$)	0	1	2

Parameter (Units)	LoB	LoD	LoQ
PLT-F ($10^3/\mu L$)	0	1	1

Body Fluids
Detections limit studies were performed for the direct measured WBC-BF, RBC-BF and TC-BF parameters on representative configurations.

For LoB testing, four blank samples were measured in five replicated each over three days using two reagent lots on a XR-10 and a XR-20 analyzer in the XR-9000 configuration.

LoD and LoQ testing, four low concentration body fluids samples were first analyzed on the Sysmex XN-29 automated hematology analyzer (K112605) to establish reference values. These low-level samples were then measured in five replicates over three days using two reagent lots on a XR-10 and XR-20 analyzer in the XR-9000 configuration.

Body Fluids Detection Limits – XR-9000 Configuration (XR-10)

Parameter (Unit)	LoB	LoD	LoQ
WBC-BF ($10^3/\mu L$)	0.001	0.002	0.002
RBC-BF ($10^6/\mu L$)	0.000	0.002	0.002
TC-BF ($10^3/\mu L$)	0.001	0.002	0.002

Body Fluids Detection Limits – XR-9000 Configuration (XR-20)

Parameter (Units)	LoB	LoD	LoQ
WBC-BF ($10^3/\mu L$)	0.001	0.002	0.002
RBC-BF ($10^6/\mu L$)	0.000	0.002	0.002
TC-BF ($10^3/\mu L$)	0.001	0.002	0.002

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Refer to the Decision Summaries for K250943 and K251371.

6. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Whole Blood

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. 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 results: XR-9000 (XR-10) versus XR-10 (standalone)

Parameter (Units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
WBC ($10^3/\mu L$)	282	0.05 - 176.78	0.9997	1.006 (0.993, 1.019)	0.018 (-0.113, 0.149)
RBC ($10^6/\mu L$)	282	2.06 - 7.86	0.9991	0.991 (0.986, 0.996)	0.062 (0.043, 0.081)
HGB (g/dL)	282	6.0 - 22.4	0.9995	0.982 (0.978, 0.986)	0.230 (0.188, 0.272)
HCT (%)	282	19.0 - 67.3	0.9989	0.990 (0.984, 0.995)	0.672 (0.469, 0.874)
MCV (fL)	282	72.7 - 113.2	0.9979	1.007 (0.998, 1.016)	-0.527 (-1.365, 0.312)
MCH (pg)	282	22.1 - 57.1	0.9884	0.937 (0.852, 1.022)	1.722 (-0.815, 4.260)
MCHC (g/dL)	282	27.8 - 57.3	0.9742	0.911 (0.740, 1.081)	2.697 (-2.851, 8.244)
PLT-I ($10^3/\mu L$)	281	2 - 2094	0.9992	1.010 (0.999, 1.021)	0.130 (-2.386, 2.645)
PLT-F ($10^3/\mu L$)	280	2 - 2434	0.9997	0.995 (0.984, 1.006)	1.605 (-1.186, 4.395)
RDW-SD (fL)	281	37.2 - 103.6	0.9980	1.002 (0.989, 1.014)	0.046 (-0.549, 0.640)
RDW-CV (%)	281	11.1 - 29.3	0.9986	1.002 (0.995, 1.008)	-0.027 (-0.119, 0.065)
MPV (fL)	255	8.1 - 14.5	0.9445	1.008 (0.953, 1.063)	-0.012 (-0.583, 0.559)
NRBC ($10^3/\mu L$)	69	0.02 - 0.81	0.9904	0.970 (0.894, 1.046)	-0.003 (-0.008, 0.002)
NRBC (%)	282	0.0 - 28.6	0.9199	0.702 (0.370, 1.034)	0.018 (-0.045, 0.081)
NEUT ($10^3/\mu L$)	281	0.00 - 55.24	0.9971	1.002 (0.972, 1.032)	0.093 (-0.069, 0.255)
LYMPH ($10^3/\mu L$)	281	0.02 - 116.40	0.9988	1.008 (0.979, 1.037)	-0.093 (-0.162, -0.023)
MONO ($10^3/\mu L$)	281	0.00 - 18.08	0.9174	1.090 (0.621, 1.559)	-0.068 (-0.476, 0.340)

Parameter (Units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
EO ($10^3/\mu L$)	281	0.00 - 1.48	0.9949	1.011 (0.991, 1.032)	0.004 (0.001, 0.007)
BASO ($10^3/\mu L$)	281	0.00 - 15.93	0.8906	1.411 (-0.745, 3.568)	-0.009 (-0.212, 0.194)
NEUT (%)	281	0.0 - 89.4	0.9946	1.010 (0.991, 1.030)	-0.137 (-1.504, 1.230)
LYMPH (%)	281	1.9 - 99.0	0.9948	1.008 (0.993, 1.022)	-0.704 (-1.002, -0.407)
MONO (%)	281	0.0 - 60.0	0.9825	1.021 (0.947, 1.095)	-0.112 (-0.751, 0.528)
EO (%)	281	0.0 - 18.5	0.9677	1.021 (0.981, 1.060)	0.002 (-0.078, 0.083)
BASO (%)	281	0.0 - 9.4	0.7882	1.184 (0.749, 1.620)	-0.080 (-0.340, 0.180)
IG ($10^3/\mu L$)	281	0.00 - 77.63	0.9998	0.987 (0.969, 1.004)	-0.020 (-0.035, -0.006)
IG (%)	281	0.0 - 47.5	0.9779	0.979 (0.956, 1.002)	-0.098 (-0.220, 0.023)
RET (%)	282	0.07 - 17.35	0.9974	0.984 (0.956, 1.012)	0.073 (0.020, 0.127)
RET ($10^6/\mu L$)	261	0.0120 - 0.5141	0.9961	0.994 (0.974, 1.014)	0.003 (0.001, 0.004)
IRF (%)	282	0.0 - 52.6	0.9628	1.003 (0.964, 1.042)	0.884 (0.352, 1.415)
RET-He (pg)	281	17.6 - 46.2	0.9857	1.025 (1.007, 1.044)	0.088 (-0.497, 0.674)
BASO (%)	281	0.0 - 9.4	0.7882	1.184 (0.749, 1.620)	-0.080 (-0.340, 0.180)
IG ($10^3/\mu L$)	281	0.00 - 77.63	0.9998	0.987 (0.969, 1.004)	-0.020 (-0.035, -0.006)
IG (%)	281	0.0 - 47.5	0.9779	0.979 (0.956, 1.002)	-0.098 (-0.220, 0.023)
RET (%)	282	0.07 - 17.35	0.9974	0.984 (0.956, 1.012)	0.073 (0.020, 0.127)
IRF (%)	282	0.0 - 52.6	0.9628	1.003 (0.964, 1.042)	0.884 (0.352, 1.415)
RET-He (pg)	281	17.6 - 46.2	0.9857	1.025 (1.007, 1.044)	0.088 (-0.497, 0.674)
IPF (%)	282	0.3 - 35.1	0.9941	1.038 (0.984, 1.092)	-0.036 (-0.208, 0.136)
IPF ($10^3/\mu L$)	277	0.4 - 138.7	0.9981	0.996 (0.927, 1.064)	0.280 (-0.187, 0.747)

Correlation and estimated Bias Results: XR-9000 (XR-20) versus XR-20 (standalone)

Parameter (units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
WBC ($10^3/\mu L$)	216	0.15 - 276.14	0.9998	0.979 (0.944, 1.014)	0.154 (-0.221, 0.529)
RBC ($10^6/\mu L$)	216	1.91 - 6.12	0.9978	0.990 (0.977, 1.003)	0.062 (0.008, 0.117)
HGB (g/dL)	216	5.0 - 19.0	0.9994	0.995 (0.991, 1.000)	0.147 (0.091, 0.204)
HCT (%)	216	15.4 - 55.1	0.9972	0.990 (0.976, 1.004)	0.709 (0.163, 1.256)
MCV (fL)	216	69.3 - 106.3	0.9969	1.013 (1.004, 1.022)	-0.740 (-1.557, 0.078)
MCH (pg)	216	22.1 - 69.7	0.9714	0.835 (0.542, 1.127)	5.064 (-3.753, 13.880)
MCHC (g/dL)	216	29.5 - 72.5	0.9615	0.705 (0.260, 1.149)	9.877 (-5.074, 24.828)
PLT-I ($10^3/\mu L$)	216	19 - 1084	0.9971	1.016 (0.986, 1.046)	-4.435 (-11.425, 2.555)
PLT-F ($10^3/\mu L$)	216	19 - 1074	0.9984	0.998 (0.974, 1.022)	-0.502 (-6.521, 5.517)
RDW-SD (fL)	216	35.5 - 99.6	0.9981	1.004 (0.994, 1.014)	0.394 (-0.066, 0.854)
RDW-CV (%)	216	11.3 - 29.2	0.9987	0.998 (0.990, 1.006)	0.201 (0.084, 0.317)
MPV (fL)	210	7.8 - 13.6	0.9698	0.980 (0.947, 1.014)	0.336 (0.009, 0.663)
NRBC ($10^3/\mu L$)	33	0.02 - 1.54	0.9985	1.217 (0.812, 1.622)	-0.010 (-0.029, 0.009)
NRBC (%)	216	0.0 - 1.0	0.3357	4.670 (-4.250, 13.590)	-0.116 (-0.380, 0.149)
NEUT ($10^3/\mu L$)	216	0.00 - 125.19	0.9994	1.018 (0.975, 1.060)	-0.139 (-0.427, 0.149)
LYMPH ($10^3/\mu L$)	216	0.02 - 17.35	0.9943	1.019 (0.989, 1.048)	-0.039 (-0.077, -0.002)
MONO ($10^3/\mu L$)	216	0.00 - 8.28	0.9796	0.997 (0.909, 1.086)	-0.013 (-0.077, 0.051)
EO ($10^3/\mu L$)	216	0.00 - 7.22	0.9985	0.957 (0.878, 1.037)	0.011 (-0.008, 0.031)
BASO ($10^3/\mu L$)	216	0.00 - 11.69	0.9998	0.883 (0.854, 0.913)	0.004 (0.001, 0.006)
NEUT (%)	216	0.0 - 91.5	0.9858	0.995 (0.946, 1.044)	0.771 (-2.458, 4.000)
LYMPH (%)	216	2.4 - 100.0	0.9921	0.961 (0.892, 1.030)	0.766 (-0.610, 2.142)
MONO (%)	216	0.0 - 26.7	0.9667	0.992 (0.938, 1.047)	0.080 (-0.483, 0.643)
EO (%)	216	0.0 - 19.7	0.9919	1.001 (0.977, 1.026)	0.056 (-0.013, 0.125)

Parameter (units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
BASO (%)	216	0.0 - 5.4	0.9343	0.858 (0.733, 0.982)	0.070 (-0.006, 0.147)
IG ($10^3/\mu L$)	216	0.00 - 107.15	0.9983	0.890 (0.663, 1.116)	0.065 (-0.132, 0.263)
IG (%)	216	0.0 - 38.8	0.9452	1.038 (0.918, 1.158)	-0.490 (-0.709, -0.271)
RET (%)	216	0.15 - 11.39	0.9971	1.045 (1.025, 1.065)	-0.044 (-0.081, -0.007)
RET ($10^6/\mu L$)	212	0.0125 - 0.3576	0.9952	1.045 (1.025, 1.065)	-0.001 (-0.003, 0.000)
IRF (%)	216	0.0 - 44.5	0.9713	1.008 (0.976, 1.041)	0.964 (0.560, 1.369)
RET-He (pg)	216	15.3 - 42.1	0.9939	1.022 (1.003, 1.042)	-0.440 (-1.073, 0.194)
IPF (%)	216	0.3 - 14.3	0.9893	1.167 (1.119, 1.214)	0.258 (0.156, 0.361)
IPF ($10^3/\mu L$)	216	0.7 - 24.0	0.9881	1.215 (1.164, 1.267)	0.379 (0.124, 0.633)

Body Fluid

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 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.

All Body Fluids Combined Summary Results of XR-9000 Configuration (XR-10)

Parameter (units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
WBC-BF ($10^3/\mu L$)	111	0.003 - 9.403	0.9983	1.015 (0.989, 1.040)	-0.004 (-0.019, 0.011)
RBC-BF ($10^6/\mu L$)	62	0.002 - 4.748	0.9988	0.993 (0.973, 1.014)	-0.006 (-0.016, 0.004)
TC-BF ($10^3/\mu L$)	112	0.003 - 9.407	0.9983	1.012 (0.986, 1.039)	-0.007 (-0.023, 0.010)

Parameter (units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
MN ($10^3/\mu L$)	115	0.003 - 3.171	0.9862	0.987 (0.908, 1.066)	-0.014 (-0.039, 0.010)
PMN ($10^3/\mu L$)	108	0.003 - 9.770	0.9981	1.072 (1.032, 1.112)	-0.013 (-0.033, 0.007)
MN (%)	123	0.0 - 100.0	0.9162	1.044 (0.998, 1.090)	-1.210 (-3.971, 1.550)
PMN (%)	123	0.0 - 100.0	0.9162	1.044 (0.998, 1.090)	-3.171 (-6.753, 0.411)

All Body Fluids Combined Summary Results of XR-9000 Configuration (XR-20)

Parameter (units)	N	Result Range	r^2	Slope (95% CI)	Intercept (95% CI)
WBC-BF ($10^3/\mu L$)	81	0.003 - 9.881	0.9971	0.988 (0.957, 1.020)	-0.064 (-0.118, -0.010)
RBC-BF ($10^6/\mu L$)	56	0.002 - 4.727	0.9998	1.002 (0.996, 1.008)	0.001 (-0.003, 0.005)
TC-BF ($10^3/\mu L$)	81	0.003 - 9.968	0.9973	0.987 (0.956, 1.018)	-0.073 (-0.127, -0.020)
MN ($10^3/\mu L$)	79	0.003 - 3.186	0.9903	0.869 (0.817, 0.922)	-0.000 (-0.026, 0.026)
PMN ($10^3/\mu L$)	78	0.003 - 8.249	0.9944	1.019 (0.972, 1.066)	-0.030 (-0.080, 0.020)
MN (%)	82	6.4 - 100.0	0.9788	1.064 (1.012, 1.116)	-4.611 (-6.878, -2.343)
PMN (%)	82	0.0 - 93.6	0.9788	1.064 (1.012, 1.116)	-1.805 (-5.227, 1.617)

Slide quality Assessment

Sysmex conducted a slide quality assessment to evaluate SP-50's ability to consistently generate uniform blood smears with preserved cellular morphology. The assessment was conducted with 20 slides prepared from samples tested in the method comparison study assessed for macroscopic quality and 10 slides assessed for microscopic quality by two reviewers. All results met the predefined acceptance criteria.

2. Matrix Comparison:

Refer to K250943 and K251371

C Clinical Studies:

1. Clinical Sensitivity:

   Refer to K250943 and K251371

2. Clinical Specificity:

   Not applicable

3. Clinical Cut-Off

   Not applicable

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Expected Values/Reference Range:

Refer to the Decision Summaries for K250943 and K251371.

E Other Supportive Instrument Performance Characteristics Data:

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.

VIII Proposed Labeling:

The labeling supports or the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.