510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K250943

B Applicant

Sysmex America, Inc.

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of a new device

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%/#, IRF, IPF, IPF#, 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 white blood cell differential, nucleated red blood cell counts, reticulocyte analysis and body fluid cell counts.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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

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

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The Sysmex XR-Series module (XR-10) is a quantitative multi-parameter hematology analyzer intended to perform tests on whole blood samples collected in K2 or K3EDTA and body fluids (pleural, peritoneal and synovial) collected in K2EDTA anticoagulant. The analyzers can also perform tests on cerebrospinal fluid, which should not be collected in any anticoagulant. The XR-Series analyzer consists of four principal units: (1) One Main Unit (XR-10) which aspirates, dilutes, mixes, and analyzes blood and body fluid samples; (2) Two Auto Sampler Units (SA-10, SA-01) which supply samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit.

B Principle of Operation:

The XR-10 analyzer performs analysis using the following methods: Radiofrequency (RF) / Direct-current (DC) Detection Method, Sheath Flow DC Detection Method, and Flow Cytometry Methods using a Semiconductor Laser and (Sodium Lauryl Sulfate) SLS-hemoglobin.

The RF/DC detection method detects the size of the cells by changes in direct-current resistance and the density of the cell interior by changes in radio-frequency resistance. In the sheath flow method, cells pass through the aperture of the detector surrounded by sheath fluid. Flow

cytometry is also used where a semiconductor laser beam is emitted to the cells passing through the flow cell. The forward scattered light is received by the photodiode, and the lateral scattered light and lateral fluorescent light are received by the photo multiplier tube. This light is converted into electrical pulses, thus making it possible to obtain cell information. Particle characterization and identification is based on detection of forward scatter, fluorescence and adaptive cluster analysis. The system carries out all processes automatically from aspiration of the sample to outputting results and uses Microsoft Windows Operating System.

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

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

C Instrument Description Information:

1. Instrument Name:

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

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-10 uses the following sampling modes:
   - Whole Blood mode, where the operator loads the sample tubes into a rack, which is then automatically transported and analyzed by the instrument. This mode automatically mixes, aspirates, and analyzes samples without removing the sample tube caps. The XR-Series Sampler Analysis mode can be performed by two samplers, namely, SA-10 and SA-01.
   - Pre-Dilution Mode is for analyzing a minute amount of whole blood or whole blood after diluting the sample to 1:7 that has been collected in a micro collection tube. Samples are analyzed with cap off in this position.
   - Low WBC Mode (LWBC) is used for retesting whole blood samples with low white blood cell counts based on user defined criteria. The counting time is set to the Whole Blood mode to increase white blood cell measurement accuracy at very low counts. The operator loads and mixes the sample tubes individually by hand (Closed and Open Cap)
   - Body Fluid Analysis Mode is for testing body fluid samples.

4. Calibration:
The XR-10 uses the following calibrators:
    - XN CAL is used for the instrument calibration of WBC, RBC, HGB, HCT, PLT and RET.
    - XN CAL PF is used for the instrument calibration of PLT-F.

5. Quality Control:
The XR-10 uses the following commercial controls:
    - XN CHECK: a trilevel control for whole blood.
    - XN CHECK BF: a bi-level control for body fluid.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Sysmex XN-Series (XN-10, XN-20)

B Predicate 510(k) Number(s):
K112605

C Comparison with Predicate(s):

Device & Predicate Device(s):	K250943	K112605
Device Trade Name	Sysmex XR-Series (XR-10) Automated Hematology Analyzer	Sysmex XN-Series
General Device Characteristic Similarities		
Intended Use/Indications For Use	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),	The XN-Series modules (XN-10, XN-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT,

	NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, 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.	NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, NRBC%/#, RET%/#, IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF parameters in cerebrospinal fluid (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Whole blood should be collected in K_2 or K_3EDTA anticoagulant and, Serous and Synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.
Specimen type	Whole Blood and Body Fluid	Same
Test Principle	Performs hematology analyses using the following methods: Radiofrequency (RF) / Direct-current (DC) Detection Method, Sheath Flow Hydro Dynamic Focusing (DC Detection) and Flow Cytometry Methods using a Semiconductor Laser, and SLS-Hemoglobin method.	Same

Parameters	<u>Whole Blood Mode:</u> 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 <u>Body Fluid Mode:</u> WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF#	Same
Reagents	CELLPACK DCL (Diluent) CELLPACK DST (Diluent) CELLPACK DFL (Diluent) Lysercell WNR (Lyse) SULFOLYSER (Lyse) Fluorocell WNR (Stain) Fluorocell WDF (Stain) Fluorocell RET (Stain) Fluorocell PLT (Stain) CELLCLEAN AUTO (Detergent)	Same
Controls/Calibrators	<u>Whole Blood</u> XN CAL (Calibrator) XN CAL PF (Calibrator) XN CHECK (Quality Control) <u>Body Fluid</u> XN CHECK BF (Quality Control)	Same
Type of Analysis	Manual analysis Sampler analysis	Same
Sampler Analysis Modes	Whole Blood mode Low WBC mode	Same

	Pre-Dilution mode Body Fluid mode	
Measuring Channels	WNR, WDF, RBC/PLT, RET, PLT-F	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
Throughput	Pre-Dilution mode: Approximately 90 samples/hour Body Fluid 40 samples/hour maximum	Same
Sample Aspiration/ Fluidic Pathway	Single Pathway	Same
General Device Characteristic Differences		
Software	Windows 10 (v.2.03.00)	Windows 7 (v.00-04)
Measuring Channels	Not available	WPC
Reagents	Lysercell WDF II (Lyse)	Lysercell WDF (Lyse)
Throughput	Whole Blood Mode: 110 samples/hour maximum depending on mode used.	Whole Blood Mode: 100 samples/hour maximum depending on mode used.

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.
- CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition.
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI H56-A, Body Fluid Analysis for Cellular Composition; Approved Guideline

- CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard– Second Edition
- IEC 60601-1-2: 2014, Medical electrical equipment − Part 1-2: General requirements for basic safety and essential performance − Collateral Standard: Electromagnetic disturbances − Requirements and tests
- IEC 61326-2-6:2020, Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- ISO 15223-1: 2021, Medical devices − Symbols to be used with information to be supplied by the manufacturer − Part 1: General requirements
- ISO 14971: 2019, Medical devices − Application of risk management to medical devices
- IEC 62304: 2015, Medical device software − Software life cycle processes
- Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Testing was conducted according to the CLSI EP05-A3 Guideline.

Whole Blood Repeatability
Whole blood repeatability studies were performed to evaluate within-run imprecision of whole blood parameter results when measured in replicates of ten on Sysmex XR-Series (XR-10) analyzers at three US clinical sites. The study was conducted using residual K2EDTA whole blood samples with concentrations targeting medical decision levels, normal, and high measurement range of WBC, HGB and PLT parameters and the low, normal, and high measurement range of RBC and HCT parameters. 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.

Parameter (units)	Sample	N	Range	Mean	SD	CV%
WBC (10^3/µL)	MDL	30	0.70 – 1.44	1.11	0.03	2.39
	Normal	30	4.79 – 7.86	6.26	0.11	1.76
	High	30	81.04 – 104.75	96.28	0.41	0.44
RBC (10^6/µL)	Low	30	1.51 – 2.03	1.84	0.01	0.77
	Normal	30	3.84 – 4.85	4.24	0.03	0.75
	High	30	6.04 – 6.50	6.26	0.05	0.74
HGB (g/dL)	MDL	30	6.20 – 7.10	6.60	0.05	0.72

Parameter (units)	Sample	N	Range	Mean	SD	CV%
	Normal	30	13.10 – 14.90	14.10	0.08	0.53
	High	30	17.45 – 21.61	19.33	0.09	0.45
HCT (%)	Low	30	13.00 – 21.80	18.40	0.16	0.90
	Normal	30	41.60 – 47.20	44.60	0.32	0.72
	High	30	52.30 – 58.10	55.60	0.39	0.71
MCV (fL)	Normal	30	78.30 – 93.90	86.30	0.26	0.30
	High 1	30	91.90 – 99.00	95.00	0.21	0.23
	High 2	30	103.60 – 121.50	113.00	0.34	0.31
MCH (pg)	Low	30	24.00 – 26.30	24.90	0.13	0.53
	Normal	30	29.30 – 33.10	31.30	0.33	1.06
	High	30	33.60 – 37.00	35.50	0.40	1.13
MCHC (g/dL)	Low	30	27.70 – 29.60	28.80	0.27	0.95
	Normal	30	30.40 – 37.60	33.20	0.29	0.88
	High	30	31.90 – 40.60	35.40	0.47	1.28
PLT-I (10^3/µL)	MDL	30	19.00 – 33.00	26.00	1.54	6.00
	Normal	30	156.00 – 241.00	205.00	5.91	2.80
	High	30	754.00 – 992.00	883.00	13.98	1.60
PLT-F (10^3/µL)	MDL	30	7.00 – 23.00	14.00	0.64	4.75
	Normal	30	149.00 – 225.00	180.00	3.75	1.96
	High	30	853.00 − 1052.00	935.00	10.01	1.08
RDW-SD (fL)	High 1	30	40.60 – 44.70	42.70	0.41	0.96
	High 2	30	50.30 – 67.10	56.50	0.64	1.17
	High 3	30	68.50 – 91.70	81.60	0.83	1.06
RDW-CV (%)	Normal	30	12.90 – 13.40	13.10	0.08	0.56
	High 1	30	15.40 – 18.80	17.10	0.16	0.91
	High 2	30	20.70 – 24.80	22.60	0.21	0.90
MPV (fL)	Low	30	8.80 – 9.50	9.10	0.08	0.89
	Normal	30	10.70 – 12.30	11.20	0.18	1.65
	High	30	11.50 – 12.40	13.40	0.21	1.64
NRBC (10^3/µL)	High 1	30	0.02 – 0.05	0.04	0.01	21.21
	High 2	30	0.03 – 0.90	0.35	0.02	15.98
	High 3	30	0.25 – 1.35	0.87	0.02	5.09
NRBC (%)	Normal 1	30	0.10 – 1.10	0.40	0.08	12.39
	Normal 2	30	0.10 – 1.70	0.90	0.09	15.55
	High	30	1.80 – 9.50	4.70	0.17	5.16
NEUT (10^3/µL)	Low	30	0.34 – 0.66	0.50	0.03	6.32

Parameter (units)	Sample	N	Range	Mean	SD	CV%
	High 1	30	6.42 – 13.60	10.52	0.15	1.36
	High 2	30	52.36 – 95.03	78.86	0.79	1.03
NEUT (%)	Low	30	11.10 – 54.50	26.00	0.62	1.82
	Normal	30	71.30 – 76.80	74.30	0.86	1.16
	High	30	86.00 – 93.90	90.10	1.01	1.12
LYMPH (10^3/µL)	Low	30	0.45 – 0.71	0.56	0.03	5.45
	Normal	30	1.12 – 2.23	1.63	0.06	4.01
	High	30	5.35 – 67.84	43.39	0.40	1.31
LYMPH (%)	Low	30	2.70 – 6.80	4.20	0.19	4.72
	Normal	30	11.60 – 40.30	26.60	0.76	3.46
	High	30	41.50 – 92.60	72.20	1.75	2.43
MONO (10^3/µL)	Low	30	0.04 – 0.35	0.14	0.02	14.63
	Normal	30	0.61 – 1.09	0.81	0.05	6.38
	High	30	1.83 – 18.48	6.85	0.54	5.64
MONO (%)	Low	30	1.40 – 7.60	3.30	0.48	13.66
	Normal	30	6.50 – 12.30	9.50	0.91	9.56
	High	30	14.8 – 54.8	32.8	1.41	5.56
EO (10^3/µL)	Normal 1	30	0.08 – 0.16	0.12	0.01	13.47
	Normal 2	30	0.08 – 0.38	0.21	0.03	15.56
	High	30	0.25 – 2.15	1.14	0.08	8.28
EO (%)	Low	30	0.10 – 2.10	0.70	0.13	10.27
	Normal	30	1.80 – 4.40	2.80	0.42	15.21
	High	30	3.20 – 10.60	6.40	1.00	15.97
BASO (10^3/µL)	Normal 1	30	0.01 – 0.03	0.02	0.01	31.28
	Normal 2	30	0.05 – 0.10	0.08	0.01	13.28
	High	30	0.25 – 0.68	0.49	0.09	17.75
BASO (%)	Normal 1	30	0.00 – 0.40	0.20	0.06	27.19
	Normal 2	30	0.40 – 1.10	0.70	0.16	23.72
	High	30	1.00 – 4.30	2.50	0.40	14.98
IG (10^3/µL)	Low	30	0.03 – 0.08	0.05	0.01	21.96
	Normal	30	0.10 – 0.72	0.41	0.06	15.46
	High	30	2.81 – 21.21	9.75	0.53	9.01
IG (%)	Normal	30	0.40 – 1.80	0.90	0.19	20.94
	High 1	30	1.60 – 5.90	3.20	0.61	18.18

Parameter (units)	Sample	N	Range	Mean	SD	CV%
	High 2	30	9.20 – 25.80	15.20	0.76	5.98
IPF (%)	Low	30	0.90 – 1.90	1.40	0.06	4.35
	Normal	30	3.90 – 6.70	5.00	0.15	3.19
	High	30	14.10 – 29.40	20.80	0.50	2.76
IPF (10^3/µL)	Level 1	30	0.60 – 1.50	1.00	0.12	12.77
	Level 2	30	6.20 – 14.40	10.60	0.44	4.30
	Level 3	30	25.6 – 88.3	48.60	1.22	2.32
RET (%)	Normal	30	0.25 – 0.96	0.49	0.04	9.37
	High 1	30	2.23 – 2.97	2.58	0.09	3.57
	High 2	30	4.65 – 10.18	6.66	0.23	3.08
RET (10^6/µL)	Low	30	0.005– 0.03	0.01	0.00	9.10
	Normal	30	0.08 – 0.10	0.09	0.00	3.68
	High	30	0.14 – 0.28	0.20	0.01	3.57
IRF (%)	Normal	30	2.30 – 6.40	4.30	0.52	12.35
	High 1	30	15.50 – 25.80	20.70	1.19	5.97
	High 2	30	29.90 – 47.00	39.30	1.36	3.40
RET-He (pg)	Low	30	23.60 – 25.40	24.70	0.27	1.09
	Normal	30	33.50 – 35.30	34.20	0.30	0.88
	High	30	39.30 – 43.60	41.00	0.21	0.50

Whole Blood Reproducibility

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

All Sites Combined				Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
Parameter (units)	Control Level	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC (10^3/µL)	1	90	3.05	0.06	1.98	0.00	0.00	0.00	0.00	0.02	0.68	0.06	2.09
	2	90	6.84	0.08	1.21	0.02	0.35	0.01	0.17	0.05	0.80	0.10	1.50

All Sites Combined				Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
Parameter (units)	Control Level	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
	3	90	16.63	0.16	0.97	0.04	0.24	0.00	0.00	0.13	0.77	0.21	1.26
RBC (10^6/µL)	1	90	2.32	0.02	1.03	0.00	0.00	0.02	0.51	0.03	1.36	0.04	1.78
	2	90	4.23	0.03	0.73	0.00	0.12	0.02	0.42	0.04	1.02	0.05	1.33
	3	90	4.97	0.03	0.75	0.02	0.33	0.00	0.00	0.03	0.65	0.05	1.05
HGB (g/dL)	1	90	5.20	0.05	0.98	0.01	0.22	0.01	0.20	0.01	0.17	0.05	1.04
	2	90	10.90	0.07	0.68	0.01	0.10	0.00	0.00	0.01	0.13	0.08	0.70
	3	90	14.40	0.06	0.40	0.01	0.06	0.02	0.12	0.06	0.38	0.08	0.57
HCT (%)	1	90	16.10	0.21	1.30	0.08	0.51	0.08	0.52	0.36	2.25	0.43	2.70
	2	90	33.00	0.29	0.88	0.19	0.56	0.13	0.39	0.62	1.89	0.72	2.19
	3	90	42.10	0.37	0.89	0.25	0.59	0.00	0.00	0.61	1.44	0.76	1.79
MCV (fL)	1	90	69.30	0.46	0.66	0.32	0.47	0.00	0.00	0.65	0.94	0.86	1.24
	2	90	78.00	0.37	0.47	0.35	0.45	0.00	0.00	0.68	0.87	0.85	1.09
	3	90	84.80	0.33	0.39	0.23	0.27	0.07	0.08	0.72	0.85	0.83	0.97
MCH (pg)	1	90	22.60	0.26	1.15	0.00	0.00	0.11	0.49	0.25	1.09	0.37	1.66
	2	90	25.90	0.20	0.76	0.02	0.07	0.11	0.41	0.29	1.14	0.37	1.43
	3	90	29.00	0.22	0.77	0.07	0.24	0.03	0.11	0.26	0.89	0.35	1.21
MCHC (g/dL)	1	90	32.60	0.47	1.46	0.08	0.25	0.15	0.45	0.67	2.05	0.84	2.57
	2	90	33.10	0.30	0.90	0.14	0.42	0.14	0.41	0.65	1.96	0.74	2.24
	3	90	34.20	0.32	0.92	0.16	0.48	0.00	0.00	0.60	1.74	0.69	2.03
PLT-I (10^3/µL)	1	90	95.00	3.50	3.70	2.40	2.57	0.00	0.00	4.30	4.49	6.00	6.36
	2	90	248.00	5.10	2.06	1.80	0.73	2.90	1.16	5.70	2.29	8.30	3.37
	3	90	583.00	9.30	1.59	1.90	0.33	0.60	0.11	9.04	1.62	13.40	2.30
PLT-F (10^3/µL)	1	90	89.00	1.40	1.58	0.30	0.35	0.0	0.00	4.60	5.24	4.9	5.48
	2	90	260.00	2.40	0.92	1.00	0.40	1.40	0.52	16.10	6.19	16.4	6.30
	3	90	584.00	4.70	0.80	0.70	0.12	1.30	0.23	32.00	5.47	32.4	5.54
	1	90	51.90	0.50	0.86	0.00	0.00	0.20	0.41	0.30	0.65	0.60	1.15

All Sites Combined				Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
Parameter (units)	**Control Level**	**N**	**Mean**	**SD**	**CV%**	**SD**	**CV%**	**SD**	**CV%**	**SD**	**CV%**	**SD**	**CV%**
RDW-SD (fL)	2	90	46.30	0.33	0.70	0.08	0.17	0.00	0.00	0.73	1.58	0.80	1.74
	3	90	52.00	0.33	0.64	0.17	0.33	0.11	0.21	0.58	1.11	0.69	1.34
RDW-CV (%)	1	90	21.00	0.14	0.68	0.12	0.58	0.00	0.00	0.09	0.42	0.21	0.98
	2	90	16.80	0.11	0.63	0.06	0.33	0.00	0.00	0.14	0.82	0.18	1.09
	3	90	17.30	0.10	0.59	0.02	0.09	0.02	0.13	0.23	1.30	0.25	1.44
MPV (fL)	1	90	9.00	0.17	1.88	0.00	0.00	0.04	0.42	0.12	1.28	0.21	2.31
	2	90	9.30	0.11	1.16	0.00	0.00	0.03	0.36	0.10	1.13	0.15	1.66
	3	90	9.10	0.07	0.77	0.00	0.00	0.03	0.28	0.13	1.45	0.15	1.67
NRBC ($10^3/\mu L$)	1	90	0.16	0.03	8.47	0.00	2.39	0.01	3.02	0.00	0.00	0.01	9.30
	2	90	0.42	0.02	4.64	0.00	0.00	0.01	1.70	0.00	0.00	0.02	4.94
	3	90	1.13	0.03	3.00	0.00	0.00	0.00	0.66	0.00	0.00	0.03	3.07
NRBC (%)	1	90	5.20	0.44	8.53	0.13	2.47	0.15	2.90	0.00	0.00	0.49	9.35
	2	90	6.20	0.29	4.70	0.00	0.00	0.09	1.40	0.00	0.00	0.30	4.90
	3	90	6.80	0.22	3.19	0.00	0.00	0.06	0.92	0.00	0.00	0.23	3.32
NEUT ($10^3/\mu L$)	1	90	1.19	0.04	3.26	0.00	0.00	0.01	0.69	0.00	0.00	0.04	3.33
	2	90	3.02	0.06	2.23	0.01	0.48	0.00	0.00	0.03	1.01	0.07	2.50
	3	90	7.95	0.16	2.05	0.06	0.80	0.00	0.00	0.06	0.82	0.18	2.34
LYMPH ($10^3/\mu L$)	1	90	1.17	0.04	3.13	0.00	0.00	0.01	0.49	0.01	0.90	0.03	3.29
	2	90	2.15	0.05	2.68	0.01	0.66	0.00	0.00	0.01	0.86	0.06	2.89
	3	90	4.42	0.08	1.82	0.00	0.00	0.00	0.00	0.04	0.81	0.08	1.99
MONO ($10^3/\mu L$)	1	90	0.26	0.016	6.33	0.00	0.00	0.00	0.00	0.00	0.00	0.02	6.33
	2	90	0.63	0.031	4.88	0.00	0.00	0.01	0.83	0.00	0.53	0.03	4.98
	3	90	1.56	0.05	3.22	0.00	0.00	0.03	1.74	0.00	0.00	0.06	3.66
EO ($10^3/\mu L$)	1	90	0.29	0.03	9.47	0.00	0.00	0.00	0.00	0.00	0.32	0.03	9.48
	2	90	0.72	0.05	8.01	0.00	0.00	0.03	0.39	0.01	2.20	0.06	8.32
	3	90	1.89	0.11	5.92	0.04	2.40	0.04	2.22	0.02	1.37	0.13	6.90

All Sites Combined				Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
Parameter (units)	Control Level	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
BASO ($10^3/\mu L$)	1	90	0.14	0.01	4.59	0.00	0.00	0.00	0.97	0.00	0.00	0.01	4.70
	2	90	0.33	0.01	3.17	0.00	0.00	0.00	0.88	0.00	1.01	0.01	3.44
	3	90	0.80	0.02	2.43	0.00	0.00	0.00	0.00	0.01	0.94	0.02	2.60
NEUT (%)	1	90	39.00	0.96	2.47	0.00	0.00	0.25	0.64	0.00	0.00	1.00	2.55
	2	90	44.20	0.85	1.93	0.00	0.00	0.00	0.00	0.13	0.29	0.86	1.96
	3	90	47.80	0.82	1.71	0.30	0.64	0.00	0.00	0.04	0.09	0.88	1.83
LYMPH (%)	1	90	38.50	1.02	2.66	0.00	0.00	0.20	0.53	0.00	0.00	1.04	2.71
	2	90	31.40	0.78	2.48	0.00	0.00	0.00	0.00	0.00	0.00	0.78	2.48
	3	90	26.60	0.38	1.42	0.02	0.09	0.00	0.00	0.06	0.24	0.38	1.44
MONO (%)	1	90	8.40	0.51	6.05	0.00	0.00	0.00	0.00	0.00	0.00	0.51	6.05
	2	90	9.10	0.42	4.57	0.00	0.00	0.03	0.32	0.00	0.00	0.42	4.58
	3	90	9.40	0.30	3.24	0.02	0.17	0.15	1.58	0.00	0.00	0.34	3.61
EO (%)	1	90	9.40	0.86	9.17	0.00	0.00	0.00	0.00	0.00	0.00	0.86	9.17
	2	90	10.50	0.83	7.93	0.00	0.00	0.10	0.96	0.25	2.39	0.88	8.34
	3	90	11.40	0.68	5.95	0.27	2.35	0.24	2.09	0.08	0.74	0.77	6.77
BASO (%)	1	90	4.70	0.20	4.15	0.00	0.00	0.04	0.94	0.02	0.33	0.20	4.27
	2	90	4.80	0.14	2.90	0.00	0.00	0.04	0.83	0.00	0.00	0.15	3.02
	3	90	4.80	0.10	2.15	0.00	0.00	0.00	0.00	0.00	0.00	0.10	2.15
IG ($10^3/\mu L$)	1	90	0.30	0.01	3.67	0.00	0.00	0.00	0.90	0.00	0.00	0.01	3.77
	2	90	0.77	0.03	3.43	0.01	0.66	0.00	0.00	0.01	0.77	0.03	3.57
	3	90	2.00	0.056	2.82	0.00	0.00	0.02	0.79	0.00	0.00	0.06	2.93
IG (%)	1	90	9.90	0.33	3.35	0.00	0.00	0.06	0.57	0.00	0.00	0.34	3.40
	2	90	11.20	0.34	3.04	0.00	0.00	0.00	0.00	0.00	0.00	0.34	3.04
	3	90	12.00	0.30	2.50	0.00	0.00	0.11	0.91	0.00	0.00	0.32	2.66
RET (%)	1	90	5.56	0.13	2.42	0.00	0.00	0.05	0.94	0.23	4.17	0.27	4.91
	2	90	2.35	0.07	3.21	0.01	0.48	0.00	0.00	0.09	4.02	0.12	5.17

All Sites Combined				Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
Parameter (units)	Control Level	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
	3	90	1.26	0.05	4.07	0.00	0.00	0.01	1.04	0.04	3.34	0.07	5.37
RET (10^6/µL)	1	90	0.13	0.00	2.64	0.00	0.00	0.00	0.91	0.00	2.78	0.00	3.95
	2	90	0.10	0.00	3.24	0.00	0.69	0.00	0.00	0.00	3.23	0.00	4.63
	3	90	0.06	0.00	4.14	0.00	0.00	0.00	1.19	0.00	3.53	0.00	5.57
IRF (%)	1	90	33.50	2.38	7.10	2.00	5.98	0.00	0.00	0.70	2.09	3.19	9.51
	2	90	40.30	2.21	5.49	1.55	3.85	0.00	0.00	0.72	1.78	2.80	6.94
	3	90	33.70	1.94	5.76	0.41	1.20	0.41	1.23	0.24	0.71	2.04	6.05
RET-He (pg)	1	90	24.00	0.14	0.59	0.14	0.58	0.06	0.25	0.11	0.47	0.24	0.99
	2	90	24.80	0.17	0.69	0.08	0.32	0.07	0.26	0.18	0.74	0.27	1.10
	3	90	25.80	0.25	0.98	0.00	0.00	0.06	0.25	0.23	0.90	0.35	1.35
IPF (%)	1	90	19.10	0.53	2.75	0.22	1.13	0.00	0.00	0.02	0.13	0.57	2.98
	2	90	19.80	0.65	3.29	0.00	0.00	0.00	0.00	0.28	1.41	0.71	3.58
	3	90	20.00	0.76	3.82	0.00	0.00	0.36	1.78	0.28	1.38	0.88	4.43
IPF (10^3/µL)	1	90	16.90	0.51	3.04	0.23	1.37	0.00	0.00	0.86	5.10	1.03	6.10
	2	90	51.50	1.80	3.49	0.00	0.00	0.40	0.77	2.87	5.56	3.41	6.61
	3	90	116.60	4.59	3.93	0.00	0.00	2.01	1.72	7.95	6.81	9.39	8.05

Body Fluid Repeatability

Body fluid repeatability studies were conducted using residual peritoneal, pleural and synovial fluid samples collected in K2EDTA anticoagulant and CSF without anticoagulant with concentrations targeting the low, and high end of the measurement range of direct measured parameters (WBC-BF, RBC-BF, TC-BF). Each sample was thoroughly mixed by gentle hand inversion and measured in replicates of ten in the body fluid mode on XR-10 analyzer at three US clinical sites. The mean, standard deviation (SD), and coefficient of variation (CV%) were calculated for each parameter. The XR-10 results met the acceptance criteria. The table below summarizes results from XR-10.

Type	Parameter (units)	Level	N	Range	Mean	SD	CV%
	WBC-BF (10^3/µL)	Low	20	0.002 – 0.010	0.005	0.00	17.58
		High	20	4.986 – 9.719	7.998	0.13	1.92
	RBC-BF (10^6/µL)	Low	20	0.002 – 0.005	0.004	0.00	12.74
		High	20	3.347 – 4.423	3.886	0.03	0.63

Type	Parameter (units)	Level	N	Range	Mean	SD	CV%
CSF	TC-BF (10^3/µL)	Low	20	0.002 – 0.011	0.006	0.00	17.41
		High	20	4.988 – 9.775	8.021	0.13	1.92
	MN (10^3/µL)	Low	20	0.002 – 0.005	0.003	0.00	22.67
		High	20	1.681 – 8.387	4.197	0.12	4.46
	PMN (10^3/µL)	Low	20	0.002 – 0.008	0.005	0.00	19.89
		High	20	4.042 – 6.196	4.793	0.14	2.94
	MN (%)	Low	20	7.0 – 18.2	11.9	0.86	8.66
		High	20	50.0 – 100.0	83.5	10.00	11.36
	PMN (%)	Low	20	11.0 – 58.8	33.2	1.86	4.94
		High	20	81.8 – 93.0	88.1	0.86	0.95
Peritoneal	WBC-BF (10^3/µL)	Low	20	0.004 – 0.010	0.007	0.00	12.87
		High	20	5.216 – 8.863	6.942	0.04	0.62
	RBC-BF (10^6/µL)	Low	20	0.002 – 0.007	0.005	0.00	10.62
		High	20	3.032 – 4.611	3.972	0.02	0.58
	TC-BF (10^3/µL)	Low	20	0.007 – 0.680	0.185	0.03	13.10
		High	20	5.217 – 8.873	6.953	0.04	0.62
	MN (10^3/µL)	Low	20	0.002 – 0.008	0.005	0.00	25.78
		High	20	1.826 – 7.976	5.136	0.12	2.63
	PMN (10^3/µL)	Low	20	0.001 – 0.023	0.007	0.00	30.15
		High	20	3.873 – 7.356	5.525	0.15	3.16
	MN (%)	Low	20	7.7 – 20.0	12.3	0.74	6.49
		High	20	60.0 – 100.0	89.8	4.81	5.54
	PMN (%)	Low	20	2.0 – 40.0	13.1	4.71	39.31
		High	20	80.0 – 92.3	87.7	0.74	0.85
Pleural	WBC-BF (10^3/µL)	Low	20	0.003 – 0.011	0.006	0.00	23.00
		High	20	5.999 – 8.765	7.753	0.06	0.78
	RBC-BF (10^6/µL)	Low	20	0.000 – 0.004	0.002	0.00	21.87
		High	20	3.653 – 4.554	4.086	0.03	0.60
	TC-BF (10^3/µL)	Low	20	0.002 – 0.011	0.005	0.00	22.37
		High	20	6.029 – 8.778	7.798	0.06	0.77
	MN (10^3/µL)	Low	20	0.002 – 0.057	0.018	0.00	21.17
		High	20	1.924 – 4.196	2.990	0.10	3.60
	PMN(10^3/µL)	Low	20	0.002 – 0.008	0.004	0.00	22.67
		High	20	3.315 – 8.226	5.786	0.07	1.40
	MN (%)	Low	20	0.0 – 33.3	16.5	3.26	16.27
		High	20	67.2 – 89.9	81.2	1.66	2.07
	PMN (%)	Low	20	10.1 – 38.7	20.4	1.87	10.77
		High	20	79.8 – 94.2	86.2	0.54	0.60
Synovial	WBC-BF (10^3/µL)	Low	20	0.003 – 0.007	0.005	0.00	15.47
		High	20	7.942 – 10.153	9.245	0.11	1.20
	RBC-BF (10^6/µL)	Low	20	0.002 – 0.004	0.003	0.00	15.13
		High	20	3.807 – 4.906	4.457	0.03	0.63
	TC-BF (10^3/µL)	Low	20	0.004 – 0.008	0.006	0.00	11.93
		High	20	7.469 – 10.159	9.080	0.13	1.47
	MN (10^3/µL)	Low	20	0.002 – 0.005	0.003	0.00	20.80
		High	20	2.212 – 7.546	4.679	0.17	2.93
	PMN (10^3/µL)	Low	20	0.001 – 0.012	0.005	0.00	31.87
		High	20	6.292 – 9.821	8.206	0.10	1.13

Type	Parameter (units)	Level	N	Range	Mean	SD	CV%
	MN (%)	Low	20	4.0 – 12.2	6.9	0.58	8.57
		High	20	53.2 – 100.0	70.5	4.15	5.37
	PMN (%)	Low	20	20.0 – 46.8	34.2	2.97	9.53
		High	20	92.8 – 97.6	95.8	0.45	0.47

Body Fluid Reproducibility

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

	All Sites Combined			Within-Run		Between-Run		Between-Day		Between-Site		Total	
Parameter (units)	Control Level	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC-BF ($10^3/\mu L$)	1	90	0.073	0.00	3.91	0.00	1.18	0.00	0.00	0.00	0.82	0.00	4.16
	2	90	0.303	0.01	2.01	0.00	0.00	0.00	0.54	0.00	1.07	0.01	2.34
RBC-BF ($10^6/\mu L$)	1	90	0.024	0.00	3.49	0.00	0.00	0.00	0.86	0.00	1.57	0.00	3.93
	2	90	0.073	0.00	1.87	0.00	0.00	0.00	0.53	0.00	1.51	0.00	2.46
MN ($10^3/\mu L$)	1	90	0.021	0.00	7.33	0.00	1.38	0.00	0.00	0.00	0.49	0.00	7.47
	2	90	0.088	0.00	3.61	0.00	0.00	0.00	0.90	0.01	1.23	0.00	3.92
MN (%)	1	90	29.10	1.74	5.98	0.34	1.17	0.00	0.00	0.28	0.97	1.80	6.17
	2	90	29.10	0.90	3.08	0.00	0.00	0.00	0.00	0.00	0.00	0.90	3.08
PMN ($10^3/\mu L$)	1	90	0.052	0.01	4.50	0.00	1.41	0.00	0.00	0.00	1.16	0.00	4.86
	2	90	0.215	0.00	2.40	0.00	0.00	0.00	0.00	0.01	0.97	0.01	2.59
PMN (%)	1	90	70.90	1.74	2.45	0.34	0.48	0.00	0.00	0.28	0.40	1.80	2.53
	2	90	70.90	0.90	1.26	0.00	0.00	0.00	0.00	0.00	0.00	0.90	1.26
TC-BF ($10^3/\mu L$)	1	90	0.073	0.00	3.91	0.00	1.18	0.00	0.00	0.00	0.82	0.00	4.16
	2	90	0.303	0.01	2.01	0.00	0.00	0.00	0.54	0.00	1.07	0.01	2.34

2. Linearity:

The study was performed according to CLSI EP06 2nd Edition guideline.

Whole Blood

Linearity studies were performed to validate the linear range of the XR-10 directly measured whole blood parameters (WBC, RBC, HGB, HCT, PLT-I and PLT-F). A minimum of nine sample dilutions were prepared including one level below and one level above the claimed linearity range. The linearity study for RET% was performed using two set of samples to

cover the upper, lower and plus one level below the measurement range. Testing was performed in triplicate in the whole blood mode on three XR-10 analyzers at one internal site. All results met predefined acceptance criteria and were determined to be acceptable.

Parameter	Linear Range
WBC ($x10^3/\mu L$)	0.03 – 440.00
RBC ($x10^6/\mu L$)	0.01 – 8.60
HGB (g/dL)	0.1 – 26.0
HCT (%)	0.1 – 75.0
PLT-I and PLT-F ($x10^3/\mu L$)	2 – 5000
RET (%)	0.00 – 30.00

Body Fluid

Linearity studies were performed to establish the linear range of the XR-10 for body fluid parameters WBC- BF, RBC-BF and TC-BF. The studies were performed using a minimum of nine sample dilutions for each measurand to including one level below and one level above claimed linear range. Testing was performed in triplicate in the body fluid mode on three XR-10 analyzers at one internal site. All results met predefined acceptance criteria and were determined to be acceptable.

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

3. Analytical Specificity/Interference:

Please refer to K251371 for interference studies.

4. Assay Reportable Range:

The reportable range was determined and validated by the method comparison study, linearity study, precision, study, and limit of quantitation study.

The resulting reportable range of each measurand is provided in Table below.

Parameter (Units)	Reportable Range
WBC ($10^3/\mu L$)	0.03−440.00
RBC	0.01−8.60

(10^6/µL)	
HGB (g/dL)	0.1−26.0
HCT (%)	0.1−75.0
PLT (10^3/µL)	2–5000
NRBC# (10^3/µL)	0.01–20.00
NRBC (%/100 WBC)	0.0–600.0
IG# (10^3/µL)	0.03–440.00
IG (%)	0.0–100.0
RET (%)	0.00–30.00
RET# (10^6/µL)	0.01–0.72
IRF (%)	0.0–100.0
IPF (%)	0.0–100.0
IPF# (10^3/µL)	0.2–500.0
WBC-BF (10^3/µL)	0.003–10.000
RBC-BF (10^6/µL)	0.002–5.000
TC-BF# (10^3/µL)	0.003–10.000

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

Whole Blood Stability
The evaluation of whole blood stability was conducted at one internal site using 20 de-identified K2EDTA venous whole blood samples. Samples were split into two sets stored at room temperature (18−26°C) and refrigerated temperature (2−8°C). Samples were tested in duplicate at baseline (T0), 6, 24, 25, 48, 49, 72 and 73 hours at both conditions. The mean, standard deviation, mean difference and percent difference from the baseline mean of each sample result were calculated for each parameter at each time interval for both conditions. The data support whole blood sample stability of 24 hours at room temperature (18−26°C) and 48 hours at refrigerated temperature (2−8°C).

Body Fluid Short-term Stability
The body fluid stability study was conducted at one external site using 12 unique de-identified leftover body fluid samples when stored at controlled room temperature. Peritoneal, pleural and synovial body fluid samples collected in K2EDTA anticoagulant and

CSF without anticoagulant were evaluated in the study. Samples were tested at baseline, 1, 2, and 4 hours at RT (18−26°C) in the body fluid analysis mode in singlet on XR-10 analyzer. Body fluid samples should be analyzed within 1 hour of collection on the XR-Series (XR-10) analyzer as demonstrated in the short-term stability study.

6. Detection Limit:

Testing was conducted by a minimum of two operators at one internal site according to the CLSI EP17-A2 approved 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 Sysmex XR-10 Automated Hematology Analyzers.

For LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots, to yield 120 total measurement results per parameter across two XR-10 analyzers.

For LoD and LoQ testing, four low concentration samples were analyzed on the Sysmex XN-20 automated hematology analyzer (K112605) to assign the reference value. The low-level samples were then measured in replicates of five over a period of three days using two reagent lots, to yield 120 total measurement results per parameter across two XR-10 Automated Hematology Analyzers. All results met the predefined acceptance criteria and were determined to be acceptable.

The maximum observed LoB, LoD, and LoQ values for whole blood parameters are summarized below:

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

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

For LoB testing, four blank samples were measured in replicates of five, over a period of three days using two reagent lots, to yield 120 total measurement results per parameter.

Low-level samples were measured in replicates of five over a period of three days using two reagent lots, to yield 120 total measurement results per parameter across two XR-10 analyzers. All results met the predefined acceptance criteria and were determined to be acceptable.

The maximum observed LoB, LoD, and LoQ values for body fluid parameters are summarized below:

Parameter	Results		
	LoB	LoD	LoQ
WBC-BF (x 10^3/µL)	0.001	0.002	0.002
RBC-BF (x 10^6/µL)	0.000	0.002	0.002
TC-BF (x 10^6/µL)	0.001	0.002	0.002

7. Assay Cut-Off:

   Not applicable

8. Accuracy (Instrument):

   Not applicable

9. Carry-Over:

   Whole Blood
   Three sets of carryover sequences were run on Sysmex XR-10 analyzers for each applicable parameter at three US clinical sites using de-identified leftover venous whole blood samples collected in 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 XR-10 whole blood mode. The study was conducted in accordance with CLSI H26-A2. The results of the whole blood carryover on XR-10 analyzers show all applicable parameters met the manufacturer's specifications.

   Body Fluid
   Carryover was conducted at three US clinical sites using de-identified 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. For each parameter, high target concentration samples were run in replicates of three (H1, H2, H3) followed by three replicates of low target concentration samples (L1, L2, L3) in XR-Series body fluid mode. The study was conducted in accordance with CLSI H26-A2. The results of body fluid carryover on XR-10 analyzers show all applicable parameters met the manufacturer's specifications.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Whole Blood

The method comparison study was conducted at three (3) US clinical sites using residual venous whole blood samples extracted from the daily routine laboratory workload to assess the performance of the Sysmex XR-Series (XR-10) Automated Hematology analyzer compared to the predicate device, Sysmex XN-20 (K112605). A total of 865 unique residual whole blood samples in K2EDTA anticoagulant from 310 pediatrics (<21 years), 551 adults (≥21 years) and 4 subjects with age not reported, including a variety of disease states (e.g., pathological WBCs, lipemia, hyperbilirubinemia, hemoglobinopathies, thrombocytopenia, thrombocytosis, etc.) were tested. Patient demographics included age ranges from 0 days to 88 years of age. Of this total, 53.7% were male, 45.8% female and 0.5% with sex not reported. A total of 362 normal (no flags, marked as negative) whole blood samples and 500 abnormal whole blood samples (contained flags, marked as positive) were tested. Samples were analyzed in singlet within 8 hours of receipt in the testing laboratory and within two hours on each analyzer.

The results of the linear regression and bias analyses between the XR-10 Whole Blood Mode and XN-20 demonstrated substantial equivalence.

Parameter (units)	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)
WBC ($10^3/\mu L$)	841	0.03 – 410.88	1.00	1.00 (0.99, 1.01)	0.06 (-0.03, 0.16)
RBC ($10^6/\mu L$)	845	0.03 – 8.50	0.99	1.00 (0.99, 1.00)	-0.03 (-0.07, 0.01)
HGB (g/dL)	843	0.2 – 25.6	0.99	0.99 (0.98, 1.00)	-0.10 (-0.21, 0.01)
HCT (%)	842	0.3 – 75.0	0.99	0.99 (0.98, 1.00)	-0.33 (-0.74, 0.06)
MCV (fL)	845	62.7 – 141.5	0.99	0.98 (0.97, 0.98)	1.71 (0.88, 2.54)
MCH (pg)	844	17.2 – 46.6	0.98	0.99 (0.97, 1.01)	-0.01 (-0.65, 0.63)
MCHC (g/dL)	844	22.2 – 41.6	0.93	0.96 (0.92, 1.00)	1.10 (-0.18, 2.39)
PLT-I ($10^3/\mu L$)	842	3 – 4930	0.99	0.98 (0.97, 1.00)	0.84 (-2.58, 4.26)
PLT-F ($10^3/\mu L$)	824	4 – 4748	0.99	1.01 (0.99, 1.03)	0.39 (-4.75, 5.54)
RDW-SD (fL)	840	29.8 – 121.5	1.00	0.96 (0.95, 0.97)	1.89 (1.30, 2.47)

Parameter (units)	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)
RDW-CV (%)	841	10.4 – 34.8	0.99	0.98 (0.94, 0.99)	0.22 (0.08, 0.38)
MPV (fL)	780	8.1 – 14.7	0.93	0.97 (0.94, 0.99)	0.08 (-0.20, 0.37)
NRBC (10^3/µL)	843	0.00 – 11.95	1.00	1.00 (0.98, 1.01)	0.00 (0.00, 0.00)
NRBC (%)	843	0.0 – 114.3	1.00	0.96 (0.93, 1.00)	0.03 (0.01, 0.05)
NEUT (10^3/µL)	834	0.00 – 300.11	1.00	0.99 (0.96, 1.03)	0.06 (-0.20, 0.33)
LYMPH (10^3/µL)	834	0.00 – 389.35	1.00	1.02 (0.98, 1.06)	0.12 (-0.02, 0.26)
MONO (10^3/µL)	834	0.00 – 71.69	0.96	0.93 (0.82, 1.05)	0.00 (-0.13, 0.12)
EO (10^3/µL)	833	0.00 – 8.11	0.98	1.03 (0.93, 1.13)	-0.004 (-0.021, 0.014)
BASO (10^3/µL)	834	0.00 – 30.10	0.98	0.83 (0.67, 1.00)	0.01 (-0.01, 0.03)
NEUT (%)	834	0.0 – 96.3	0.99	1.00 (0.99, 1.01)	-0.07 (-0.67, 0.52)
LYMPH (%)	834	0.0 – 96.7	0.99	1.01 (1.00, 1.02)	0.18 (-0.05, 0.43)
MONO (%)	834	0.0 – 79.6	0.97	0.94 (0.89, 0.98)	0.14 (-0.20, 0.49)
EO (%)	833	0.0 – 47.5	0.99	1.00 (0.97, 1.03)	0.03 (-0.03, 0.08)
BASO (%)	834	0.0 – 8.4	0.94	0.86 (0.79, 0.93)	0.01 (-0.03, 0.05)
IG (10^3/µL)	834	0.00 – 155.97	1.00	0.99 (0.96, 1.02)	0.00 (-0.03, 0.03)
IG (%)	834	0.0 – 44.8	0.96	0.97 (0.93, 1.01)	0.02 (-0.05, 0.09)
RET (%)	824	0.12 – 23.10	0.98	0.99 (0.95, 1.03)	0.03 (-0.03, 0.09)
RET (10^6/µL)	793	0.01 – 0.54	0.97	0.97 (0.91, 1.04)	0.00 (-0.00, 0.01)
IRF (%)	824	0.0 – 56.7	0.97	0.97 (0.95, 0.99)	-1.66 (-1.92, -1.39)
RET-He (pg)	822	17.00 – 51.30	0.97	0.92 (0.90, 0.94)	1.29 (0.61, 1.96)
IPF (%)	824	0.4 – 37.9	0.99	0.98 (0.95, 1.00)	-0.07 (-0.17, 0.03)

Parameter (units)	N	Result Range	r	Slope (95% CI)	Intercept (95% CI)
IPF ($10^3/\mu L$)	819	0.2 – 256.4	0.99	1.03 (0.95, 1.12)	-0.66 (-1.63, 0.30)

Body fluid

A method comparison study was conducted to assess the performance of Sysmex XR-10 Body Fluid Mode when compared to the predicate device, Sysmex XN-20 (K112605). A total of 397 residual body fluid samples (111 CSF, 101 pleural, 114 peritoneal, and 71 synovial) were tested at a total of three US sites. All body fluids (peritoneal, pleural, and synovial) except CSF were collected in K2EDTA anticoagulant and were run in singlet on the XN-20 and within two hours on the XR-10 analyzer. Patient demographics includes age ranges from 9 days to 86 years of age and comprised of 208 males, 160 females and 29 with unknown sex. Samples covered clinical medical decision levels, and to the extent possible, of the full measuring ranges of the XR-10 analyzer. The results of the linear regression analysis between XR-10 in Body Fluid Mode and XN-20 analyzer for all body fluids (CSF, peritoneal, pleural and synovial) are shown below.

Sample Type	Parameter (units)	N	Result Range	r	Slope (95%CI)	Intercept (95% CI)
CSF	WBC-BF ($10^3/\mu L$)	76	0.003 – 9.178	1.00	1.00 (0.96, 1.02)	0.00 (-0.02, 0.02)
	RBC-BF ($10^6/\mu L$)	61	0.002 – 4.875	1.00	1.00 (0.98, 1.00)	0.02 (-0.02, 0.06)
	MN ($10^3/\mu L$)	70	0.003 – 4.074	0.87	1.73 (0.72, 2.73)	-0.45 (-1.19, 0.20)
	MN (%)	90	0.0 – 100.0	0.80	1.01 (0.88, 1.14)	-2.03 (-6.79, 2.68)
	PMN ($10^3/\mu L$)	61	0.003 – 8.393	0.98	0.95 (0.88, 1.02)	-0.04 (-0.12, 0.03)
	PMN (%)	90	0.0 – 100.0	0.80	1.01 (0.88, 1.14)	0.79 (-9.20, 10.79)
	TC-BF ($10^3/\mu L$)	78	0.003 – 9.192	1.00	1.00 (0.96, 1.02)	0.00 (-0.02, 0.02)
Peritoneal	WBC-BF ($10^3/\mu L$)	107	0.004 – 9.766	1.00	0.99 (0.98, 1.01)	0.01 (-0.00, 0.02)
	RBC-BF ($10^6/\mu L$)	70	0.002 – 4.801	1.00	0.99 (0.98, 1.01)	0.00 (0.00, 0.01)
	MN ($10^3/\mu L$)	108	0.003 – 5.689	0.96	1.12 (0.93, 1.31)	-0.02 (-0.08, 0.05)
	MN (%)	109	0.6 – 100.0	0.95	0.98 (0.90, 1.02)	1.41 (-0.73, 3.55)

Sample Type	Parameter (units)	N	Result Range	r	Slope (95%CI)	Intercept (95% CI)
	PMN (10^3/µL)	97	0.003 – 8.469	0.99	0.95 (0.90, 1.00)	0.02 (-0.01, 0.05)
	PMN (%)	109	0.0 – 99.4	0.95	0.98 (0.94, 1.02)	0.51 (-2.41, 3.43)
	TC-BF (10^3/µL)	107	0.004 – 9.774	1.00	0.99 (0.98, 1.01)	0.01 (0.00, 0.03)
Pleural	WBC-BF (10^3/µL)	95	0.005 – 9.996	1.00	1.01 (0.99, 1.03)	-0.01 (-0.03, 0.02)
	RBC-BF (10^6/µL)	72	0.002 – 4.691	1.00	0.99 (0.98, 1.00)	0.00 (0.00, 0.00)
	MN (10^3/µL)	97	0.004 – 5.240	0.98	1.22 (1.09, 1.30)	-0.12 (-0.21, -0.04)
	MN (%)	99	9.2 – 100.0	0.91	1.00 (0.96, 1.04)	0.31 (-3.80, 4.43)
	PMN (10^3/µL)	92	0.006 – 8.862	0.99	0.93 (0.86, 1.01)	0.01 (-0.04, 0.06)
	PMN (%)	99	0.0 – 90.8	0.91	1.00 (0.96, 1.04)	-0.63 (-2.44, 1.21)
	TC-BF (10^3/µL)	94	0.006 – 9.437	1.00	1.01 (0.98, 1.03)	-0.01 (-0.03, 0.02)
Synovial	WBC-BF (10^3/µL)	55	0.004 – 9.780	1.00	1.00 (0.97, 1.02)	0.03 (-0.00, 0.07)
	RBC-BF (10^6/µL)	56	0.002 – 4.801	1.00	0.97 (0.97, 0.99)	0.00 (0.00, 0.00)
	MN (10^3/µL)	61	0.004 – 4.803	0.93	1.24 (0.94, 1.55)	-0.15 (-0.34, 0.03)
	MN (%)	65	0.0 – 93.1	0.95	0.99 (0.90, 1.090	0.30 (-1.5, 2.20)
	PMN (10^3/µL)	56	0.003 – 8.694	0.98	0.99 (0.96, 1.02)	-0.03 (-0.14, 0.07)
	PMN (%)	65	6.9 – 100.0	1.00	0.99 (0.90, 1.09)	0.20 (-7.95, 8.36)
	TC-BF (10^3/µL)	55	0.004 – 9.783	1.00	1.00 (0.98, 1.02)	0.03 (-0.01, 0.07)

2. Matrix Comparison:

Whole Blood Anticoagulant Comparison (K2EDTA vs. K3EDTA)

Comparability between K2EDTA vs. K3EDTA anticoagulated whole blood samples on the Sysmex XR-10 hematology analyzer were conducted at one internal site using 46 paired K2 and K3EDTA venous whole blood samples. Testing was run in singlet in the automated whole blood sampling mode using CBC+DIFF+RET+PLT-F+WPC mode between K2EDTA

and K3EDTA anticoagulant samples from each donor and completed within 2 hours. The results of the regression analysis and bias analyses between K2EDTA and K3EDTA venous whole blood samples met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the two anticoagulants.

Venous Whole Blood to Capillary Whole Blood Comparison

A comparison study was conducted to evaluate the equivalency of venous whole blood samples collected in K2EDTA anticoagulant tubes to capillary whole blood samples collected in K2EDTA micro-collection tubes on Sysmex XR-10 analyzers. The study was conducted using 46 paired venous and capillary (finger stick) prospectively collected samples drawn from consented subjects representative of patient samples, across medical decision levels, and to the extent possible of the full analytical measurement range of direct measured parameters (WBC, RBC, HGB, HCT and PLT) in singlet in the automated whole blood sampling mode using CBC+DIFF+RET+PLT-F+WPC mode at one internal site. The results of the regression analysis and bias analyses between venous K2EDTA and capillary K2EDTA whole blood samples met predefined correlation and coefficient and/or bias limits for all applicable parameters and demonstrate equivalency between the two sample matrices.

C Clinical Studies:

1. Clinical Sensitivity:

Flagging study was conducted at each of the three external clinical sites from the method comparison study for the Sysmex XR-Series (XR-10) Automated Hematology analyzer. Patient samples representing a variety of abnormal conditions were evaluated. Each sample was assessed on XR-10, predicate Sysmex XN-20 and manual differential counts from peripheral blood smear. Three blood film slides were prepared for each sample for manual microscopy. The flagging results from the Sysmex XR-10 Automated Hematology Analyzer for normal (no flags) and abnormal (flags present) were compared to predicate and manual differential counts, respectively. 2x2 tables were constructed to determine flagging capabilities of XR-10 for both distributional and morphological abnormalities. The flagging results met the predefined acceptance criteria and are presented in the following tables.

Flagging results in comparison to manual microscopy

Category	N	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)	Efficiency (95% CI)
Any Distribution Flag	705	325	55	213	112	74.37 (70.01, 8.40)	79.48 (74.14, 84.15)	76.31 (73.00, 79.41)
Any Morphology Flag	780	199	188	353	40	83.26 (77.91, 87.77)	65.25 (61.07, 69.26)	70.77 (67.44, 73.94)
Any Flag (combined)	780	417	102	171	90	82.25 (78.62, 85.48)	62.64 (56.60, 68.39)	75.38 (72.20, 78.37)

Sensitivity = 100 * TP / (TP+FN)
Specificity = 100 * TN / (TN+FP)
Efficiency = 100 * (TP+TN) / (TP+TN+FP+FN)

Flagging results in comparison to predicate

Category	N	TP	FP	TN	FN	PPA (95% CI)	NPA (95% CI)	OPA (95% CI)
Any Distribution Flags	834	468	14	326	26	94.74 (92.38, 96.53)	95.88 (93.19, 97.73)	95.20 (93.53, 96.55)
Any Morphology Flags	844	383	60	369	32	92.29 (89.29, 94.67)	86.01 (82.37, 89.15)	89.10 (86.80, 91.12)
Any Flag (combined)	845	557	32	235	21	96.37 (94.50, 97.74)	88.01 (83.50, 91.66)	93.73 (91.88, 95.27)

PPA (Positive Percent Agreement) = 100 * TP / (TP+FN)
NPA (Negative Percent Agreement) = 100 * TN / (TN+FP)
OA (Overall Percentage Agreement) = 100 * (TP+TN) / (TP+TN+FP+FN)

2. Clinical Specificity:

   Refer to Clinical Sensitivity

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

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Whole Blood – Adult Reference Intervals

Verification of adult reference intervals was conducted on the Sysmex XR-Series (XR-10) Automated Hematology analyzer to demonstrate comparability of whole blood reference intervals for adult population (>21 years) to ranges established for Sysmex XE-5000 (K071967). 132 samples (58 males and 74 females) were tested at one site. The results of the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the adult male and female and were determined to be acceptable.

Parameter (units)	Adult Male	Adult Female
WBC ($10^3/\mu L$)	4.23 − 9.07	3.98 − 10.04
RBC ($10^6/\mu L$)	4.63 − 6.08	3.93 − 5.22
HGB (g/dL)	13.07 − 17.50	11.20 −15.70
HCT (%)	40.10 − 51.00	34.10 − 44.90
MCV (fL)	79.00 − 92.20	79.40 − 94.80
MCH (pg)	25.70 − 32.20	25.6 − 32.20

Parameter (units)	Adult Male	Adult Female
MCHC (g/dL)	32.30 − 36.50	32.2 − 35.50
PLT−I (10^3/µL)	163.00 – 337.00	182.00 −369.00
PLT-F (10^3/µL)	163.00 – 337.00	182.00 −369.00
RDW−SD (fL)	35.10 − 43.90	36.40 − 46.30
RDW−CV (%)	11.60 − 14.40	11.70 −14.40
MPV (fL)	9.40 − 12.40	9.40 − 12.30
NRBC (10^3/µL)	0.00 − 0.01	0.00 − 0.012
NRBC (%)	0.00 − 0.20	0.00 − 0.20
NEUT# (10^3/µL)	1.78 − 5.38	1.56 − 6.13
LYMPH (10^3/µL)	1.32 − 3.57	1.18 − 3.74
MONO (10^3/µL)	0.30 − 0.82	0.24 − 0.86
EO (10^3/µL)	0.04 − 0.54	0.04 − 0.36
BASO (10^3/µL)	0.01 − 0.08	0.01 − 0.08
IG# (10^3/µL)	0.01 − 0.25	0.01 − 0.23
NEUT%	34.00 − 67.90	34.00 − 71.10
LYMPH (%)	21.80 − 53.10	19.30 −51.70
MONO (%)	5.30 − 12.20	4.70 − 12.50
EO (%)	0.80 − 7.00	0.70 − 5.80
BASO (%)	0.20 − 1.20	0.10 − 1.20
IG (%)	0.10 − 1.70	0.10 − 1.60
RET (%)	0.51 − 1.81	0.50 − 1.70
RET (10^6/µL)	0.03 − 0.09	0.016 − 0.08
IRF (%)	2.30 − 13.40	4.23 − 9.07
RET−He (pg)	28.20 − 36.60	28.20 − 36.60
IPF (%)	0.90 − 11.20	0.90 −11.20

Whole Blood − Verification of Pediatric Reference Intervals

A reference interval verification study was performed for the pediatric population by referring to literature[1]. A total of 196 pediatric samples including each subpopulation: 40 neonates (birth–28 days); 55 infants (>28 days–2 years); 60 children (>2 years–12 years); and 41 adolescents (>12 years–21 years) were included in the study. The results of the proposed reference intervals overlapped the 95% confidence intervals (lower and upper limit) of the pediatric datasets and were determined to be acceptable.

Parameter (units)	Neonate (0−28 days)	Infant (>28 days–2 years)	Child (>2 –12 years)	Adolescent (>12 –21 years)
WBC (10^3/µL)	6.54 − 23.17	3.74 − 14.77	3.44 − 13.69	3.13 − 12.43
RBC (10^6/µL)	3.00 − 5.76	2.87 − 5.51	3.11 − 5.41	3.38 − 5.88
HGB (g/dL)	9.80 − 19.70	8.90 – 14.10	10.2 − 14.7	10.40 – 16.40
HCT (%)	29.20 – 56.60	25.80 − 43.85	25.64 − 44.40	27.80 – 48.70

[1] Wong, E., Brugnara, C., Straseski, J., Kellogg, M., & Adeli, K. 2021. Pediatric Reference Intervals. 8th ed., Hematology Tests (pp. 209-267).

Parameter (units)	Neonate (0−28 days)	Infant (>28 days–2 years)	Child (>2 –12 years)	Adolescent (>12 –21 years)
MCV (fL)	89.55 − 112.60	68.20 − 97.22	67.83 − 92.76	70.70 – 96.00
MCH (pg)	30.65 − 38.75	19.45 − 33.36	19.50 − 31.10	21.1 − 32.10
MCHC (g/dL)	33.00 − 36.00	29.80 – 36.00	29.60 − 35.60	29.70 − 35.13
PLT-I (10^3/µL)	114.00 – 555.00	175.00 – 591.00	167.00 – 504.00	152.00 – 426.00
PLT-F (10^3/µL)	114.00 – 555.00	175.00 – 591.00	167.00 – 504.00	152.00 – 426.00
RDW-CV (%)	13.75 − 19.85	11.40 − 20.70	11.60 – 21.10	11.50 – 19.33
MPV (fL)	9.10 − 12.40	8.40 − 12.30	8.40 − 12.60	8.95 − 12.75
NRBC (10^3/µL)	0.00 – 3.72	0.00 − 0.05	0.00 − 0.02	0.00 − 0.03
NEUT (10^3/µL)	1.29 − 11.02	1.06 – 8.76	1.24 − 9.22	1.35 – 9.19
LYMPH (10^3/µL)	1.43 − 5.87	0.68 – 8.17	0.94 − 5.80	1.03 − 3.94
MONO (10^3/µL)	0.31 − 2.18	0.18 – 3.52	0.28 – 1.30	0.28 − 1.15
EO (10^3/µL)	0.05 − 0.80	0.00 – 1.03	0.00 − 0.97	0.01 − 0.72
BASO (10^3/µL)	0.01 − 0.13	0.01 – 0.09	0.01 − 0.10	0.01 − 0.09
NEUT (%)	18.60 – 76.30	13.2 – 71.40	23.35 – 71.30	32.24 − 73.16
LYMPH (%)	15.00 − 65.00	17.60 – 76.40	13.82 − 66.41	14.04 − 53.38
MONO (%)	6.00 − 28.40	3.00 − 34.80	4.40 – 29.20	4.60 − 15.11
EO (%)	0.25 − 7.45	0.00 – 12.80	0.0 – 12.70	0.20 – 11.2
BASO (%)	0.1 − 1.05	0.10 – 1.5	0.10 − 1.20	0.20 − 1.40
IG (10^3/µL)	0.02 − 0.56	0.00 − 0.13	0.00 − 0.09	0.00 − 0.09
IG (%)	0.1 − 3.55	0.00 − 1.70	0.00 − 1.10	0.00 − 1.20
RET (%)	0.40 – 21.00	0.80 − 3.80	0.75 − 2.80	0.80 − 2.20
RET (10^6/µL)	0.02 − 0.35	0.03 − 0.12	0.03 − 0.11	0.04 − 0.10
IRF (%)	11.40 − 35.1	11.40 − 25.80	2.50 − 17.00	2.50 − 17.00
RET-He (pg)	19.40 − 40.70	19.10 − 34.60	23.60 − 33.90	27.05 – 35.20
IPF (%)	1.70 – 17.40	0.40 − 16.90	1.00 − 4.80	1.40 – 7.10

Body Fluid – Verification of Reference Intervals

A verification study was conducted using a minimum of 20 normal CSF and 20 normal Synovial fluids to verify normal reference ranges cited from published literature[2]. According to Kjeldsberg (1993), reference intervals for RBC counts are not applicable in body fluid, and therefore, no reference interval for RBC has been established.

F Other Supportive Instrument Performance Characteristics Data:

Manual mode Normal tube position vs. Manual mode Micro-collection tube position

A comparison study was conducted to determine the presence or absence of matrix effects between K2EDTA tubes and micro-collection tubes on Sysmex XR-10 analyzers. The study was conducted using residual and prospectively collected K2EDTA venous whole blood samples at one internal site using seventy paired venous whole blood samples. Sample distribution included clinical medical decision levels and to the extent possible of the analytical measuring range.

[2] Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd ed. Chicago, Il: ASCP Press. 1993

K2EDTA venous whole blood samples were first analyzed in singlet in the Manual Mode Normal Tube position. Within 2 hours of analysis of samples in the normal tube position, the samples were mixed and transferred to micro-collection tubes (without anticoagulant) and analyzed in the Manual Mode Micro-collection tubes (without anticoagulant) and analyzed in the Manual Mode Micro-collection tube position. The results of the regression analysis and bias analyses between K2EDTA tube and micro collection tubes on XR-10 Analyzer met predefined correlation and coefficient and/or bias limits for all applicable parameters.

Whole Blood Mode to Pre-dilute Mode Comparison

Comparability between whole blood mode to pre-dilute mode was conducted at one internal site using 45 de-identified residual whole blood samples and system diluent to create 1:7 dilution samples. Each whole blood sample was run in singlet in the whole blood mode of the Sysmex XR−10 analyzer. Within 2 hours of analysis in the whole blood mode, a 1:7 dilution was prepared for each sample by pipetting 600 µL of system diluent (CELLPACK DCL) into 4 mL plain top tubes using calibrated displacement pipettes and adding 100 µL of whole blood using a new tip to create a 1:7 dilution. Each dilution sample was mixed by gentle hand inversion and run in singlet in the pre-dilution mode. Results in the pre-dilution mode are automatically multiplied by 7 before results are displayed. The results from the whole blood mode sample tubes were compared to the corresponding results of the dilution sample tubes for the same patient sample. The results of the comparison data met predefined acceptance criteria for all applicable parameters and demonstrate equivalency between the whole blood and pre-dilution modes on the XR-Series (XR−10) analyzer.

Predilute Mode Normal Tube to Micro-collection Tube Comparison

The comparison study was conducted at one internal site using 40 de-identified residual whole blood samples and system diluent to create dilution samples. A 1:7 dilution was prepared for each whole blood sample by pipetting 600 µL of system diluent (CELLPACK DCL) into 4 mL plain top tubes using calibrated displacement pipettes. 100 µL of whole blood was added to 4 mL tubes to create a 1:7 dilution for each whole blood sample. Each sample dilution was analyzed in singlet in the Pre-dilution mode of the Sysmex XR-10 analyzer. Within 2 hours of analysis, the 4 mL tube dilution samples were remixed then transferred to micro collection tubes without additives, then placed in the Micro collection tube holder position and analyzed in singlet in the Pre-dilution mode. Results in the pre-dilution mode are automatically multiplied by 7 before results are displayed. The results from the dilution sample tubes were compared to the corresponding results of the micro collection dilution sample tubes for the same patient sample. The results of the comparison data met predefined acceptance criteria for all applicable parameters and demonstrate equivalency between the Normal and Micro collection tube holder positions on the XR-Series (XR-10) analyzer.

Low WBC Mode Normal Tube to Micro collection Tube Comparison

Comparability between Low WBC Mode Normal Tube to Micro collection was conducted at one internal site using 43 residual de-identified venous whole blood samples with WBC concentrations less than 4.50 x 10^3/µL. Each whole blood sample was run in singlet in the Low

WBC whole blood mode on the XR-10 analyzer. Within 2 hours of analysis in the Low WBC whole blood mode, the whole blood samples were remixed then transferred to micro collection tubes without anticoagulant then placed in the Micro collection tube holder position and run in singlet in the Low WBC whole blood mode. The results from the Low WBC whole blood Normal tube holder sample position were compared to the corresponding results of the Micro collection tube holder sample position for the same patient sample. The results of the comparison data met predefined acceptance criteria for all applicable parameters and demonstrate equivalency between Low WBC mode Normal tube and Micro collection tube holder positions on the XR-Series (XR-10) analyzer.

VIII Proposed Labeling:

The labeling supports 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.