510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K160538

B. Purpose for Submission:

Clearance of a new device

C. Manufacturer and Instrument Name:

Sysmex America Inc., Sysmex® XN-L Automated Hematology Analyzer

D. Type of Test or Tests Performed:

The XN-L analyzer classifies and enumerates 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, RET%/#, 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 CSF, peritoneal, pleural and synovial fluids.

E. System Descriptions:

1. Device Description:

   The Sysmex XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates whole blood and body fluid parameters by means of electrical impedance, laser light scattering, and fluorescent labeling. Tests are performed on whole blood samples collected in K2 or K3 EDTA anticoagulant and body fluids (peritoneal, pleural and synovial) collected in K2EDTA anticoagulant and cerebrospinal fluid that is not collected in anticoagulant. The instrument consists of two principal units: (1) Main Unit which will aspirate, dilute, mix, and analyze whole blood and body fluid samples and (2) Pneumatic Unit which supplies pressure and vacuum to the analyzer.

   The XN-L has an external monitor with touch screen capability that is used to operate the instrument and process data from the Main Unit. The monitor also allows operator interfacing with the instrument by use of a panel keyboard

2. Principles of Operation:

   The XN-L analyzer performs analysis using the following methods: DC Sheath Flow

Detection method, Flow Cytometry method using a semiconductor laser, and SLS (cyanide-free sodium lauryl sulfate) hemoglobin method. Particle characterization and identification is based on detection of forward scatter, fluorescence, and adaptive cluster analysis. The XN-L analyzer automatically classifies cells from whole blood and body fluids and carries out all processes automatically from aspiration of the sample to result output.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X____

4. Specimen Identification:

   Specimen identification input is manual (by operator) or by barcode reader

5. Specimen Sampling and Handling:

   There are two modes of sample introduction: (1) Sampler Mode; (2) Manual Mode. In the Sampler Mode 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 their caps. The Sampler Mode is used for processing of whole blood samples. In the Manual Mode, there are two sample tube holders: (1) Normal sample tube holder; (2) Micro collection tube holder. In this mode the operator loads and mixes the samples tubes individually by hand. The samples in the Manual Mode can be analyzed with the cap on or off. The Manual Mode is used for processing whole blood and body fluid samples.

6. Calibration:

   The XN CAL™ calibrator (K160585) is used for calibration of the instrument for WBC, RBC, HGB, HCT, PLT and RET. XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21, XN-L) analyzers. Calibration is performed as needed (e.g., when QC data is fluctuating) to ensure accuracy of the system.

7. Quality Control:

   The XN-L CHECK (K160586) is used as quality control (three levels) for Sysmex XN-L

analyzers. XN-L CHECK™ is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), and stabilized platelet component(s) in a preservative medium.

XN CHECK (K160590) is used as quality control (three levels) for Sysmex XN series (XN-10, XN-11, XN-20, XN-21, XN-L) analyzers. XN CHECK™ is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), stabilized platelet component(s), and stabilized nucleated red blood cell component(s) in a preservative medium.

XN CHECK BF (K160588) is used as quality control (two levels) for Sysmex XN series (XN-10, XN-11, XN-20, XN-21, XN-L) analyzers. Assayed parameters include: WBC-BF, RBC-BF, MN%, PMN%, TC-BF#.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5220, Automated differential cell counter

2. Classification:

   Class II

3 Product code:

   GKZ, Counter, differential cell

4. Panel:

   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

   The Sysmex XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates the following

parameters in venous and capillary whole blood: WBC, RBC, HGB, HCT, MCV, MCH,MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV, RDW-SD, MPV, RET%/#,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, peritoneal, pleural, and synovial fluids. Whole blood should be collected in K2 or K3EDTA anticoagulant and peritoneal, pleural, and synovial fluids in K2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.

The performance of this device has not been established in pediatric patients under the age of 2 years.

2. Special Conditions for Use Statement(s):

   For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Sysmex XN-Series (XN-10, XN-20) Automated Hematology Analyzer, K112605

2. Comparison with Predicate Device:

Similarities		
Item	Device: XN-L	Predicate: XN-Series (XN-10)[a] K112605
Intended Use	The Sysmex® XN-L analyzer is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-L analyzer classifies and enumerates 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, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBCBF, RBC-BF, MN%/#, PMN%/#, and TC-BF# parameters in CSF, peritoneal, pleural and synovial fluids. Whole blood should	The XN-Series modules (XN-10, XN-20) are quantitative multi-parameter automated hematology analyzers intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XN-Series modules classify and enumerate the following parameters in whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT,NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV,RDW-SD, MPV, NRBC%/#, RET%/#,IPF, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode

Similarities		
Item	Device: XN-L	Predicate: XN-Series (XN-10)[a] K112605
	be collected in K_2 or K_3 EDTA anticoagulant and peritoneal, pleural and synovial fluids in K_2EDTA anticoagulant to prevent clotting of fluid. The use of anticoagulants with CSF specimens is neither required nor recommended.	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 K2 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 and Body Fluids (CSF and Peritoneal, Pleural, Synovial Fluids)	Same
Test Principle	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS hemoglobin method.	Same
Parameters	Whole Blood Mode: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, RDWCV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He# Body Fluid Mode: WBC-BF, RBC-BF, MN%/#, PMN%/#,TC-BF#	Same
Reagents	CELLPACK®DCL (Diluent) CELLPACK® DFL (Diluent) Lysercell™ WDF (Lyse) Fluorocell™ WDF (Stain) Fluorocell™ RET (Stain) SULFOLYSER® (Lyse)	Same
Analysis Modes	<u>Sampler Analysis Mode</u> (rack autoloader) Whole Blood Mode <u>Manual Analysis Mode</u> Whole Blood Mode LWBC Analysis Mode Pre-Dilute Analysis Mode Body Fluid Mode	Same

Similarities		
Item	Device: XN-L	Predicate: XN-Series (XN-10)[a] K112605
Sample Aspiration/Fluidic Pathway	Single Pathway	Same
Measuring Channels	RBC/PLT, HGB, RET, WDF	Same
Controls/Calibrators/ Linearity Material	Whole Blood XN CHECK™ 3 Levels (K160590) XN CAL™ (K160585) Body Fluid XN CHECK™ BF 2 Levels (K160588) Whole Blood Linearity Range Check X III (K960557) Retic Chex (K000115)	Same
Cleaning Detergent	CELLCLEAN AUTO™	Same
Software/ Hardware	Rules based rerun/reflex	Same

Differences		
Item	Device: XN-L	Predicate
Parameters	Not Available	PLT (PLT-F), NRBC%/#, IPF
Reagents	Not Available Not Available Not Available	K112605 Lysercell™ WNR (Lyse) Fluorocell™ WNR (Stain) Fluorocell™ PLT (Stain)
Measuring Channels	Not Available	WNR, PLT-F
Controls/Calibrators	Not Available XN-L CHECK™ [b]	XN CAL™ PF – (K120747) Not Available
Throughput	Whole Blood Mode 60 samples/hour maximum depending on mode used. Body Fluid Mode 30 samples/hour maximum	Whole Blood Mode 100 samples/hour maximum depending on mode used. Body Fluid Mode 40 samples/hour maximum
Sample Aspiration Volumes	Sampler Mode - 25 µL Manual (Closed Cap) Mode - 25 µL Manual (Open Cap) Mode - 25 µL Dilution Mode - 70 µL Body Fluid Mode - 70 µL	Sampler Mode - 88 µL Manual (Closed Cap) Mode - 88 µL Manual (Open Cap) Mode - 88 µL Dilution Mode - 70 µL Body Fluid Mode - 88 µL

[a] Intended use for the predicate analyzer was cleared in submission K112605. All information listed for the predicate analyzer refers to the XN-10 module.
[b] Control material specific for the XN-L analyzer.

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures, Approved Guideline - Third Edition

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures; A Statistical Approach; Approved Guideline -Third Edition

CLSI EP09-A3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition

CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - 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 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 Analyzer; Approved Guideline – Second Edition

J. Performance Characteristics*:*

1. Analytical Performance:

a. Method Comparison:

Whole Blood Studies

The method comparison study includes a total of 426 residual K2EDTA whole blood samples collected across three U.S. sites. All samples were run in the Automated Sampling Mode in singlet on the XN-10 analyzer and within 2 hours on the XN-L analyzer. Samples covered clinical medical decision levels and, to the extent possible, the full reportable measuring ranges of the XN-L analyzer. The regression lines were calculated using Deming linear regression analysis including 95% confidence intervals (CI) and estimates of the bias/difference for each parameter was determined in accordance with CLSI EP09-A3 approved guideline.

All sites combined

N	Result Range	Correlation Coefficient	Slope	95% CI	Intercept	95% CI
WBC (10^3/µL)	0.04 to 510.50	0.9996	0.989	0.986 to 0.991	0.006	-0.073 to 0.085
RBC (10^6/µL)	0.02 to 8.90	0.9827	0.982	0.964 to 0.999	0.081	0.012 to 0.151

N	Result Range	Correlation Coefficient	Slope	95% CI	Intercept	95% CI
HGB (g/dL)	0.0 to 27.5	0.9830	0.990	0.972 to 1.007	0.23	0.03 to 0.44
HCT (%)	0.2 to 74.5	0.9797	0.975	0.956 to 0.994	1.14	0.48 to 1.81
MCV (fL)	60.3 to 131.1	0.9974	1.033	1.025 to 1.040	-2.35	-2.99 to -1.71
MCH (pg)	15.3 to 53.3	0.9737	0.970	0.949 to 0.991	1.08	0.45 to 1.72
MCHC (g/dL)	25.4 to 58.0	0.9195	0.838	0.805 to 0.870	5.36	4.29 to 6.43
PLT (10^3/µL)	0 to 5480	0.9974	1.008	1.001 to 1.015	2.1	0.2 to 4.1
RDW-SD (fL)	33.9 to 96.3	0.9974	1.013	1.006 to 1.020	-0.10	-0.45 to 0.24
RDW-CV (%)	11.0 to 27.8	0.9980	0.997	0.991 to 1.003	-0.04	-0.13 to 0.06
MPV (fL)	7.9 to 14.5	0.9489	0.993	0.962 to 1.024	0.14	-0.20 to 0.48
NEUT# (10^3/µL)	0.00 to 133.45	0.9984	0.992	0.986 to 0.997	-0.062	-0.145 to 0.020
LYMPH# (10^3/µL)	0.03 to 165.37	0.9968	0.982	0.974 to 0.989	0.111	0.047 to 0.176
MONO# (10^3/µL)	0.00 to 42.79	0.9942	1.026	1.015 to 1.037	-0.038	-0.070 to -0.007
EO# (10^3/µL)	0.00 to 7.48	0.9959	0.975	0.967 to 0.984	0.000	-0.005 to 0.004
BASO# (10^3/µL)	0.00 to 14.53	0.9350	0.604	0.583 to 0.625	0.034	0.017 to 0.050
IG# (10^3/µL)	0.00 to 140.03	0.9998	0.970	0.968 to 0.971	-0.018	-0.035 to 0.000
NEUT%	0.0 to 95.7	0.9886	1.011	0.997 to 1.026	-1.31	-2.27 to -0.35
LYMPH%	0.8 to 96.0	0.9879	1.024	1.009 to 1.039	0.11	-0.32 to 0.55
MONO%	0.0 to 83.7	0.9775	1.003	0.982 to 1.023	0.12	-0.10 to 0.34
EO%	0.0 to 29.1	0.9903	0.994	0.980 to 1.007	0.00	-0.04 to 0.05
BASO%	0.0 to 18.2	0.4006	0.334	0.280 to 0.388	0.50	0.41 to 0.59
IG%	0.0 to 43.5	0.9231	0.968	0.931 to 1.004	-0.18	-0.39 to 0.03
RET# (10^6/µL)	0.0035 to 0.4576	0.9821	1.045	1.026 to 1.064	-0.00618	-0.00804 to -0.00432
RET%	0.11 to 31.74	0.9914	1.074	1.060 to 1.088	-0.217	-0.260 to -0.174
IRF (%)	0.0 to 62.9	0.9723	1.056	1.032 to 1.079	0.23	-0.28 to 0.75
RETHE (pg)	14.9 to 42.5	0.9655	1.039	1.013 to 1.066	-3.24	-4.08 to -2.41

Flagging Studies

Flagging analysis was conducted to evaluate the flagging capabilities of the XN-L analyzer using the flagging results obtained from the samples used in the method comparison study. A total of 219 normal (no flags, marked as negative) whole blood samples and 207 abnormal whole blood samples (contained flags, marked as positive) were tested. Samples were divided into 2 categories: (1) Negative – normal, healthy subjects - No flags, Negative judgment and (2) Positive – subjects with positive morphology/differential - Flags present, Positive judgment.

All sites combined

All Sites (N=426)		XN-10		
		Positive (Abnormal)	Negative (Normal)	Total
XN-L	Positive (Abnormal)	199	15	214
	Negative (Normal)	8	204	212
	Total	207	219	426

All Sites (N=426)	95% CI
Positive Percent Agreement	96.1 (92.5 – 98.3)
Negative Percent Agreement	93.2 (89.0 – 96.1)
% Overall Agreement	94.6 (92.0 – 96.6)

Body Fluids

The body fluid method comparison study includes a total of 419 residual body fluids samples (106 CSF, 103 pleural, 115 peritoneal, and 95 synovial) collected across three U.S. sites. All samples were collected in K2EDTA anticoagulant with the exception of CSF. All samples were run in the Body Fluid Mode in singlet on the XN-10 and within 2 hours on the XN-L analyzer. Samples covered clinical medical decision levels and, to the extent possible, the full reportable measuring ranges of the XN-L analyzer. The samples are not representative of any specific patient population.

Patient demographics included age ranges from 1 month to 99 years of age comprised of 213 males and 206 females. Detailed demographics of the data analysis are provided in Table 20-40. The regression lines were calculated using Deming linear regression analysis including 95% CI and estimates of the bias/difference for each parameter was determined in accordance with the CLSI EP09-A3 approved guideline.

The Body Fluid Mode reports WBC-BF, RBC-BF, MN#/%, PMN#/%, and TC-BF#. The TC-BF represents a total nucleated cell count and includes cells in the WBC-BF + HF-BF (high fluorescent) areas. The WBC-BF is a white blood cell count that includes neutrophils, lymphocytes, monocytes, eosinophils, and basophils. As per laboratory practice, manual counts for body fluids include macrophages as part of the monocyte count. Cells such as mesothelial and lining cells are not included in the WBC count.

CSF Fluid Method Comparison

	Result Range	Correlation Coefficient	SEE	Slope	95% CI	Intercept	95% CI
WBC-BF x 10^3/µL	0.000 to 21.383	0.9978	0.2383	0.992	0.979 to 1.005	-0.0129	-0.0624 to 0.0365
RBC-BF x 10^6/µL	0.000 to 3.713	0.9999	0.0119	1.014	1.011 to 1.017	0.0007	-0.0019 to 0.0033
TC-BF x 10^3/µL	0.000 to 21.434	0.9978	0.2380	0.992	0.980 to 1.005	-0.0135	-0.0629 to 0.0358
MN# x 10^3/µL 103/µL	0.000 to 6.833	0.9990	0.0355	1.048	1.039 to 1.057	-0.0091	-0.0164 to -0.0018
PMN# x 10^3/µL	0.000 to 19.488	0.9978	0.2104	0.983	0.970 to 0.996	-0.0084	-0.0519 to 0.0351
MN%	0.0 to 100.0	0.6769	26.89	0.994	0.832 to 1.156	3.16	-4.92 to 11.23
PMN%	0.0 to 100.0	0.6769	26.89	0.994	0.832 to 1.156	-2.59	-14.12 to 8.94

Peritoneal Fluid Method Comparison

	Result Range	Correlation Coefficient	SEE	Slope	95% CI	Intercept	95% CI
WBC-BF x 10^3/µL	0.000 to 19.517	0.9968	0.2040	0.939	0.925 to 0.953	0.0559	0.0143 to 0.0975
RBC-BF x 10^6/µL	0.000 to 5.276	0.9998	0.0148	0.989	0.986 to 0.993	0.0033	0.0004 to 0.0062
TC-BF x 10^3/µL	0.000 to 19.547	0.9967	0.2069	0.938	0.924 to 0.953	0.0531	0.0107 to 0.0955
MN# x 10^3/µL	0.000 to 2.854	0.9918	0.0842	1.024	0.999 to 1.049	0.0038	-0.0145 to 0.0221
PMN# x 10^3/µL	0.000 to 16.669	0.9969	0.1659	0.928	0.915 to 0.942	0.0290	-0.0041 to 0.0621
MN%	0.0 to 96.5	0.9796	6.21	1.013	0.974 to 1.051	0.9700	-1.61 to 3.56
PMN%	3.5 to 100.0	0.9796	6.21	1.013	0.974 to 1.051	-2.2400	-4.20 to -0.28

Pleural Fluid Method Comparison

	Result Range	Correlation Coefficient	SEE	Slope	95% CI	Intercept	95% CI
WBC-BF x 10^3/µL	0.000 to 18.064	0.9991	0.1353	0.989	0.980 to 0.997	0.0040	-0.0257 to 0.0337
RBC-BF x 10^6/µL	0.000 to 3.563	0.9996	0.0210	0.993	0.988 to 0.999	-0.0015	-0.0060 to 0.0031
TC-BF x 10^3/µL	0.000 to 18.082	0.9990	0.1430	0.987	0.978 to 0.996	0.0011	-0.0303 to 0.0326
MN# x 10^3/µL	0.000 to 3.211	0.9966	0.0611	0.986	0.970 to 1.002	0.0024	-0.0122 to 0.0170
PMN# x 10^3/µL	0.000 to 15.162	0.9991	0.1097	0.993	0.985 to 1.001	-0.0019	-0.0250 to 0.0212
MN%	0.0 to 97.6	0.9445	11.04	1.030	0.962 to 1.099	-0.99	-5.76 to 3.79
PMN%	2.4 to 100.0	0.9445	11.04	1.030	0.962 to 1.099	-2.04	-5.47 to 1.38

Synovial Fluid Method Comparison

	Result Range	Correlation Coefficient	SEE	Slope	95% CI	Intercept	95% CI
WBC-BF x 10^3/µL	0.000 to 75.467	0.9977	0.9377	0.994	0.980 to 1.008	0.0442	-0.1778 to 0.2662
RBC-BF x 10^6/µL	0.000 to 5.813	0.9996	0.0301	0.998	0.992 to 1.003	0.0020	-0.0053 to 0.0093
TC-BF x 10^3/µL	0.000 to 76.467	0.9974	0.9948	0.991	0.976 to 1.006	0.0563	-0.1791 to 0.2917
MN# x 10^3/µL	0.000 to 10.248	0.9817	0.3958	1.143	1.098 to 1.188	-0.0990	-0.1951 to -0.0030
PMN# x 10^3/µL	0.000 to 67.173	0.9954	1.1745	0.986	0.967 to 1.006	0.0248	-0.2503 to 0.2998
MN%	0.0 to 94.7	0.9729	6.96	1.044	0.993 to 1.095	0.57	-1.67 to 2.82
PMN%	5.3 to 100.0	0.9729	6.96	1.044	0.993 to 1.095	-4.98	-8.64 to -1.32

CI=confidence interval; SEE=standard error of the estimate.

b. Precision/Reproducibility:

Repeatability-Whole Blood

Within-run precision (repeatability) studies were performed in accordance with the CLSI EP05-A3 approved guideline using residual K2EDTA whole blood samples around medical decision levels and the upper and lower limit of the analytical measuring range. Ten replicates of each sample were tested in the Whole Blood Manual Mode at three clinical sites.

Reproducibility –Whole Blood

Reproducibility studies were performed to evaluate the within-run, between-run, between-day, between-site, and total precision of the XN-L analyzer. Testing was performed using 3 levels of each whole blood control material (XN-L CHECK and XN CHECK). Each level was run in the Whole Blood Automated Sampling Mode in duplicate twice each day for a minimum of 20 days using a single calibration and reagent lot at each of the three test sites. The results were analyzed in accordance with the CLSI EP05-A3 approved guideline and met the acceptance criteria as displayed in the tables below.

All Sites – XN-L check

Device: XN-L XN-L CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control Level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC ($10^3/\mu L$)	Level 1	240	2.44	0.050	2.05	0.017	0.70	0.000	0.00	0.018	0.75	0.056	2.29
	Level 2	240	6.92	0.121	1.75	0.000	0.00	0.033	0.48	0.041	0.59	0.132	1.91
	Level 3	240	16.19	0.171	1.06	0.018	0.11	0.070	0.43	0.087	0.53	0.205	1.27
RBC ($10^6/\mu L$)	Level 1	240	2.40	0.015	0.62	0.000	0.00	0.009	0.36	0.006	0.23	0.018	0.76
	Level 2	240	4.50	0.044	0.99	0.000	0.00	0.020	0.43	0.029	0.65	0.057	1.26
	Level 3	240	5.46	0.029	0.53	0.007	0.13	0.015	0.28	0.020	0.37	0.039	0.72
HGB (g/dL)	Level 1	240	6.3	0.05	0.78	0.00	0.00	0.01	0.18	0.04	0.62	0.06	1.01
	Level 2	240	13.0	0.12	0.93	0.00	0.00	0.04	0.28	0.00	0.02	0.13	0.97
	Level 3	240	17.7	0.06	0.33	0.04	0.20	0.02	0.13	0.07	0.42	0.10	0.58
HCT (%)	Level 1	240	17.9	0.12	0.67	0.11	0.64	0.13	0.71	0.12	0.68	0.24	1.35
	Level 2	240	36.2	0.31	0.86	0.22	0.61	0.24	0.65	0.21	0.57	0.49	1.36
	Level 3	240	48.6	0.24	0.49	0.39	0.81	0.21	0.43	0.40	0.81	0.64	1.32
MCV (fL)	Level 1	240	74.8	0.23	0.31	0.43	0.58	0.44	0.58	0.48	0.64	0.81	1.09
	Level 2	240	80.6	0.19	0.24	0.51	0.64	0.30	0.38	0.47	0.58	0.78	0.97
	Level 3	240	89.0	0.13	0.14	0.65	0.73	0.42	0.47	0.66	0.74	1.03	1.16
MCH (pg)	Level 1	240	26.1	0.25	0.95	0.00	0.00	0.07	0.26	0.24	0.92	0.35	1.35
	Level 2	240	28.8	0.19	0.64	0.07	0.24	0.06	0.23	0.22	0.76	0.30	1.05
	Level 3	240	32.5	0.20	0.61	0.09	0.29	0.02	0.07	0.26	0.80	0.34	1.05

Device: XN-L XN-L CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	**Control Level**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
MCHC (g/dL)	Level 1	240	35.0	0.34	0.97	0.24	0.68	0.21	0.59	0.30	0.85	0.55	1.57
	Level 2	240	35.8	0.24	0.68	0.27	0.75	0.19	0.52	0.24	0.67	0.47	1.32
	Level 3	240	36.5	0.21	0.57	0.34	0.92	0.07	0.20	0.36	0.98	0.54	1.48
PLT (10^3/µL)	Level 1	240	65	3.0	4.57	0.0	0.00	2.8	4.38	1.5	2.28	4.4	6.73
	Level 2	240	244	5.5	2.27	0.6	0.23	3.1	1.27	1.9	0.79	6.7	2.73
	Level 3	240	591	7.7	1.30	2.9	0.49	5.0	0.84	2.0	0.34	9.8	1.66
RDW-SD (fL)	Level 1	240	49.0	0.32	0.65	0.08	0.16	0.18	0.36	0.00	0.00	0.37	0.76
	Level 2	240	44.2	0.23	0.53	0.21	0.49	0.11	0.26	0.07	0.17	0.35	0.78
	Level 3	240	44.4	0.29	0.65	0.31	0.69	0.19	0.44	0.24	0.53	0.52	1.17
RDW-CV (%)	Level 1	240	17.8	0.10	0.55	0.07	0.42	0.15	0.87	0.12	0.68	0.23	1.30
	Level 2	240	15.0	0.08	0.51	0.05	0.35	0.06	0.38	0.06	0.38	0.12	0.82
	Level 3	240	13.7	0.07	0.53	0.03	0.25	0.06	0.43	0.04	0.29	0.11	0.78
MPV (fL)	Level 1	240	10.7	0.30	2.84	0.11	1.03	0.05	0.49	0.10	0.89	0.34	3.19
	Level 2	240	10.0	0.14	1.40	0.00	0.00	0.04	0.39	0.07	0.71	0.16	1.61
	Level 3	240	9.7	0.06	0.61	0.03	0.31	0.02	0.21	0.06	0.63	0.09	0.96
NEUT# (10^3/µL)	Level 1	240	1.12	0.031	2.76	0.015	1.37	0.000	0.00	0.007	0.61	0.035	3.14
	Level 2	240	3.36	0.075	2.22	0.000	0.00	0.020	0.61	0.023	0.68	0.081	2.40
	Level 3	240	8.44	0.133	1.58	0.000	0.00	0.033	0.39	0.051	0.60	0.146	1.73
LYMPH# (10^3/µL)	Level 1	240	0.69	0.027	3.96	0.009	1.26	0.004	0.58	0.008	1.11	0.030	4.34
	Level 2	240	1.65	0.048	2.88	0.024	1.46	0.000	0.00	0.010	0.62	0.054	3.29
	Level 3	240	3.03	0.070	2.30	0.030	0.97	0.035	1.16	0.045	1.50	0.095	3.14
MONO# (10^3/µL)	Level 1	240	0.19	0.016	8.39	0.000	0.00	0.000	0.00	0.000	0.26	0.016	8.40
	Level 2	240	0.58	0.027	4.71	0.000	0.00	0.003	0.50	0.000	0.00	0.027	4.74
	Level 3	240	1.39	0.040	2.90	0.009	0.66	0.015	1.06	0.000	0.00	0.044	3.16
EO# (10^3/µL)	Level 1	240	0.30	0.013	4.42	0.008	2.59	0.000	0.00	0.002	0.62	0.015	5.16
	Level 2	240	0.89	0.039	4.38	0.000	0.00	0.016	1.76	0.000	0.00	0.042	4.72
	Level 3	240	2.23	0.073	3.29	0.027	1.20	0.000	0.00	0.009	0.40	0.078	3.52
BASO# (10^3/µL)	Level 1	240	0.15	0.010	6.60	0.000	0.00	0.000	0.00	0.001	0.59	0.010	6.62
	Level 2	240	0.44	0.024	5.41	0.000	0.00	0.000	0.00	0.003	0.73	0.024	5.46
	Level 3	240	1.10	0.047	4.25	0.000	0.00	0.014	1.24	0.004	0.39	0.049	4.44
NEUT (%)	Level 1	240	45.8	0.97	2.12	0.00	0.00	0.13	0.29	0.05	0.11	0.98	2.15
	Level 2	240	48.6	0.61	1.26	0.30	0.62	0.00	0.00	0.00	0.00	0.68	1.40
	Level 3	240	52.1	0.60	1.15	0.00	0.00	0.09	0.18	0.17	0.32	0.63	1.21
LYMPH (%)	Level 1	240	28.1	0.96	3.41	0.42	1.48	0.00	0.00	0.15	0.52	1.05	3.76
	Level 2	240	23.8	0.58	2.45	0.27	1.14	0.00	0.00	0.06	0.26	0.65	2.71
	Level 3	240	18.7	0.40	2.15	0.12	0.64	0.15	0.78	0.23	1.20	0.50	2.66
MONO (%)	Level 1	240	7.9	0.63	7.90	0.00	0.00	0.00	0.00	0.00	0.00	0.63	7.90

Device: XN-L XN-L CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control Level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
	Level 2	240	8.4	0.38	4.54	0.00	0.00	0.06	0.68	0.04	0.48	0.39	4.61
	Level 3	240	8.6	0.23	2.67	0.08	0.91	0.05	0.56	0.03	0.34	0.25	2.90
EO (%)	Level 1	240	12.1	0.46	3.79	0.28	2.28	0.00	0.00	0.00	0.00	0.54	4.43
	Level 2	240	12.8	0.51	3.96	0.00	0.00	0.19	1.50	0.00	0.00	0.54	4.24
	Level 3	240	13.7	0.44	3.19	0.16	1.16	0.03	0.22	0.00	0.00	0.47	3.40
BASO (%)	Level 1	240	6.0	0.37	6.16	0.00	0.00	0.00	0.00	0.04	0.62	0.37	6.19
	Level 2	240	6.4	0.32	5.07	0.00	0.00	0.05	0.73	0.00	0.00	0.33	5.12
	Level 3	240	6.8	0.27	4.02	0.00	0.00	0.09	1.36	0.04	0.60	0.29	4.29
IG# (10^3/µL)	Level 1	240	0.30	0.017	5.66	0.000	0.00	0.003	1.00	0.000	0.00	0.017	5.75
	Level 2	240	0.92	0.054	5.84	0.000	0.00	0.000	0.00	0.008	0.91	0.054	5.91
	Level 3	240	2.31	0.128	5.55	0.000	0.00	0.023	1.02	0.006	0.25	0.131	5.65
IG (%)	Level 1	240	12.4	0.65	5.26	0.00	0.00	0.15	1.17	0.00	0.00	0.67	5.39
	Level 2	240	13.3	0.74	5.60	0.00	0.00	0.00	0.00	0.05	0.39	0.74	5.61
	Level 3	240	14.3	0.79	5.50	0.00	0.00	0.16	1.09	0.00	0.00	0.80	5.61
RET (%)	Level 1	240	5.25	0.149	2.83	0.077	1.46	0.000	0.00	0.232	4.42	0.286	5.45
	Level 2	240	2.09	0.065	3.10	0.000	0.00	0.000	0.00	0.072	3.43	0.097	4.63
	Level 3	240	0.85	0.035	4.07	0.019	2.27	0.000	0.00	0.025	2.91	0.047	5.49
RET# (10^6/µL)	Level 1	240	0.1258	0.00368	2.92	0.00201	1.60	0.00000	0.00	0.00534	4.24	0.00679	5.40
	Level 2	240	0.0938	0.00323	3.44	0.00000	0.00	0.00039	0.42	0.00260	2.78	0.00417	4.44
	Level 3	240	0.0466	0.00190	4.08	0.00113	2.42	0.00000	0.00	0.00117	2.52	0.00250	5.37
IRF (%)	Level 1	240	19.1	1.39	7.30	1.73	9.08	1.64	8.63	1.80	9.42	3.29	17.29
	Level 2	240	22.1	1.42	6.41	1.82	8.26	1.40	6.34	2.16	9.79	3.46	15.66
	Level 3	240	18.9	1.56	8.26	1.56	8.22	1.50	7.93	1.86	9.85	3.25	17.20
RET-He (pg)	Level 1	240	22.1	0.11	0.48	0.08	0.38	0.13	0.60	0.56	2.55	0.60	2.69
	Level 2	240	22.7	0.19	0.84	0.00	0.00	0.17	0.74	0.56	2.46	0.61	2.70
	Level 3	240	23.9	0.31	1.30	0.00	0.00	0.31	1.28	0.55	2.32	0.71	2.95

XN-Check All sites combined

Device: XN-L XN CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC (10^3/µL)	Level 1	240	3.01	0.063	2.07	0.032	1.05	0	0	0.006	0.21	0.07	2.34
	Level 2	240	7.15	0.109	1.53	0	0	0.01	0.14	0.033	0.46	0.114	1.6
	Level 3	240	17	0.159	0.93	0	0	0.048	0.28	0.063	0.37	0.177	1.04

Device: XN-L XN CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
RBC (10^6/µL)	Level 1	240	2.37	0.018	0.78	0	0	0.007	0.31	0.01	0.43	0.022	0.94
	Level 2	240	4.39	0.025	0.58	0.013	0.29	0.014	0.31	0.011	0.24	0.033	0.75
	Level 3	240	5.33	0.023	0.43	0.024	0.46	0	0	0.013	0.25	0.036	0.68
HGB (g/dL)	Level 1	240	6.1	0.04	0.72	0	0	0.01	0.24	0.04	0.58	0.06	0.96
	Level 2	240	12.5	0.06	0.49	0	0	0.02	0.18	0.08	0.61	0.1	0.81
	Level 3	240	16	0.06	0.38	0.02	0.14	0.03	0.16	0.1	0.66	0.13	0.79
HCT (%)	Level 1	240	17.9	0.14	0.8	0.06	0.36	0.12	0.65	0.14	0.75	0.24	1.33
	Level 2	240	36.2	0.2	0.55	0.2	0.56	0.24	0.67	0.21	0.57	0.43	1.18
	Level 3	240	45.9	0.21	0.46	0.23	0.51	0.2	0.43	0.29	0.62	0.47	1.02
MCV (fL)	Level 1	240	75.7	0.25	0.33	0.31	0.41	0.36	0.47	0.55	0.73	0.77	1.01
	Level 2	240	82.4	0.15	0.18	0.3	0.37	0.4	0.48	0.62	0.75	0.81	0.98
	Level 3	240	86.2	0.21	0.25	0.31	0.35	0.34	0.39	0.61	0.71	0.79	0.92
MCH (pg)	Level 1	240	25.7	0.24	0.93	0.07	0.29	0.02	0.09	0.26	1.03	0.36	1.42
	Level 2	240	28.4	0.18	0.63	0.1	0.37	0.06	0.21	0.23	0.82	0.32	1.12
	Level 3	240	30	0.17	0.57	0.14	0.48	0	0	0.27	0.9	0.35	1.17
MCHC (g/dL)	Level 1	240	33.9	0.34	1	0.1	0.31	0.24	0.7	0.34	1	0.55	1.61
	Level 2	240	34.5	0.22	0.63	0.19	0.54	0.23	0.66	0.3	0.87	0.47	1.37
	Level 3	240	34.8	0.22	0.63	0.2	0.57	0.16	0.47	0.32	0.91	0.46	1.32
PLT (10^3/µL)	Level 1	240	59	2.7	4.54	0.7	1.25	3	5.13	2.1	3.62	4.6	7.85
	Level 2	240	256	5.6	2.18	1.9	0.76	2.6	1.01	1.1	0.43	6.5	2.55
	Level 3	240	568	8.4	1.48	3.5	0.62	3.1	0.54	4.3	0.75	10.5	1.85
RDW-SD (fL)	Level 1	240	45.6	0.38	0.83	0	0	0.2	0.45	0.11	0.24	0.44	0.97
	Level 2	240	45.7	0.24	0.52	0.2	0.44	0.2	0.44	0.29	0.63	0.47	1.02
	Level 3	240	47.9	0.27	0.57	0.11	0.23	0.13	0.27	0.19	0.39	0.37	0.78
RDW-CV (%)	Level 1	240	16.5	0.1	0.61	0.05	0.31	0.09	0.57	0.09	0.55	0.17	1.05
	Level 2	240	15.1	0.07	0.44	0.03	0.18	0.05	0.32	0.04	0.25	0.09	0.63
	Level 3	240	15.2	0.08	0.54	0.05	0.31	0.03	0.22	0.02	0.14	0.1	0.68
MPV (fL)	Level 1	240	8.6	0.3	3.51	0	0	0.19	2.26	0.05	0.59	0.36	4.22
	Level 2	240	10	0.12	1.23	0.02	0.2	0.06	0.59	0.01	0.13	0.14	1.38
	Level 3	240	9.8	0.07	0.73	0	0	0.03	0.32	0.03	0.34	0.08	0.86
NEUT# (10^3/µL)	Level 1	240	1.14	0.038	3.37	0.016	1.44	0	0	0	0	0.042	3.66
	Level 2	240	2.92	0.074	2.54	0	0	0.018	0.61	0.005	0.18	0.076	2.62
	Level 3	240	7.53	0.15	1.99	0.022	0.29	0.063	0.84	0	0	0.164	2.18
LYMPH#	Level 1	240	1.09	0.036	3.27	0.013	1.22	0.005	0.45	0.018	1.68	0.043	3.9

Device: XN-L XN CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
(10^3/µL)	Level 2	240	2.35	0.054	2.29	0	0	0.006	0.23	0.042	1.79	0.069	2.92
	Level 3	240	4.7	0.082	1.74	0	0	0.018	0.38	0.067	1.42	0.107	2.28
MONO# (10^3/µL)	Level 1	240	0.34	0.024	7.04	0	0	0.009	2.64	0.007	2.08	0.027	7.8
	Level 2	240	0.77	0.033	4.33	0.002	0.2	0.007	0.89	0.018	2.33	0.039	5
	Level 3	240	1.92	0.052	2.72	0.019	0.98	0.024	1.25	0.021	1.12	0.064	3.34
EO# (10^3/µL)	Level 1	240	0.28	0.021	7.43	0.008	2.92	0	0	0.003	0.93	0.023	8.04
	Level 2	240	0.72	0.054	7.45	0	0	0.02	2.83	0	0	0.057	7.97
	Level 3	240	1.83	0.128	7.02	0.047	2.56	0.051	2.81	0	0	0.146	7.98
BASO# (10^3/µL)	Level 1	240	0.16	0.012	7.55	0	0	0.005	2.92	0	0	0.013	8.1
	Level 2	240	0.39	0.024	6.04	0	0	0.004	1.04	0	0	0.024	6.13
	Level 3	240	1.03	0.056	5.45	0.017	1.6	0	0	0	0	0.059	5.68
NEUT (%)	Level 1	240	37.9	1.02	2.69	0.38	1	0	0	0.12	0.32	1.09	2.89
	Level 2	240	40.8	0.85	2.07	0	0	0.28	0.68	0.06	0.16	0.89	2.19
	Level 3	240	44.3	0.77	1.73	0.13	0.3	0.35	0.78	0.06	0.13	0.85	1.93
LYMPH (%)	Level 1	240	36.3	0.96	2.65	0.22	0.6	0.13	0.36	0.52	1.44	1.12	3.1
	Level 2	240	32.8	0.61	1.84	0.06	0.18	0.18	0.54	0.45	1.38	0.78	2.37
	Level 3	240	27.6	0.38	1.38	0.15	0.56	0.13	0.47	0.29	1.04	0.52	1.87
MONO (%)	Level 1	240	11.3	0.74	6.53	0	0	0.3	2.68	0.27	2.39	0.84	7.45
	Level 2	240	10.8	0.44	4.11	0	0	0.12	1.09	0.28	2.6	0.54	4.98
	Level 3	240	11.3	0.29	2.58	0.11	0.98	0.12	1.04	0.17	1.49	0.37	3.31
EO (%)	Level 1	240	9.4	0.67	7.12	0.17	1.84	0	0	0.07	0.7	0.69	7.39
	Level 2	240	10.1	0.71	7.11	0	0	0.25	2.52	0	0.03	0.76	7.55
	Level 3	240	10.8	0.76	7.11	0.22	2.07	0.3	2.83	0	0	0.85	7.93
BASO (%)	Level 1	240	5.2	0.38	7.3	0	0	0.13	2.46	0.03	0.59	0.4	7.72
	Level 2	240	5.5	0.32	5.91	0	0	0.08	1.38	0	0	0.33	6.07
	Level 3	240	6.1	0.33	5.4	0.12	1.99	0	0	0.02	0.32	0.35	5.76
IG# (10^3/µL)	Level 1	240	0.3	0.014	4.57	0.005	1.63	0	0	0	0	0.015	4.85
	Level 2	240	0.76	0.027	3.54	0	0	0.005	0.69	0	0	0.027	3.61
	Level 3	240	1.97	0.066	3.35	0	0	0.006	0.28	0	0	0.066	3.36
IG (%)	Level 1	240	9.9	0.42	4.18	0.15	1.53	0	0	0	0	0.44	4.45
	Level 2	240	10.6	0.35	3.26	0	0	0.07	0.62	0.04	0.36	0.35	3.34
	Level 3	240	11.6	0.35	3.06	0.06	0.56	0.02	0.14	0	0	0.36	3.11
RET (%)	Level 1	240	5.55	0.138	2.48	0	0	0.029	0.53	0.211	3.79	0.253	4.56
	Level 2	240	2.26	0.062	2.75	0.02	0.87	0.014	0.61	0.07	3.1	0.097	4.28

Device: XN-L XN CHECK, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
	Level 3	240	0.9	0.039	4.33	0	0	0.011	1.17	0.028	3.1	0.049	5.45
RET# (10^6/µL)	Level 1	240	0.1313	0.00336	2.56	0	0	0.00093	0.71	0.0044	3.35	0.00561	4.27
	Level 2	240	0.0992	0.00278	2.81	0.00067	0.67	0.00096	0.97	0.0029	2.92	0.00419	4.22
	Level 3	240	0.048	0.00214	4.45	0	0	0.00062	1.29	0.0014	2.91	0.00263	5.47
IRF (%)	Level 1	240	25.1	1.46	5.83	2.6	10.35	0	0	2.06	8.19	3.63	14.43
	Level 2	240	28.6	1.51	5.3	2.45	8.58	1.48	5.17	1.93	6.75	3.77	13.19
	Level 3	240	23.8	1.81	7.62	1.56	6.54	1.3	5.45	1.33	5.58	3.02	12.72
RET-He (pg)	Level 1	240	22.8	0.12	0.52	0.14	0.6	0.16	0.69	0.54	2.38	0.59	2.6
	Level 2	240	23.5	0.18	0.75	0	0	0.16	0.67	0.55	2.35	0.6	2.56
	Level 3	240	24.6	0.28	1.15	0.13	0.51	0.13	0.51	0.61	2.48	0.7	2.83

Repeatability-Body Fluids

Within-run precision studies were performed at 3 clinical sites in accordance with the CLSI EP05-A3 approved guideline using two high- and two low-residual body fluid samples for CSF, pleural, peritoneal, and synovial fluids around medical decision levels and the upper and lower limit of the analytical measuring range. Pleural, peritoneal, and synovial fluids were collected in K2EDTA anticoagulant. Each sample was run 10 consecutive times in the Body Fluid Mode at three clinical sites.

Reproducibility-Body Fluids

Precision studies were performed on the XN-L analyzer Body Fluid Mode using two levels of quality control material (Level 1 and Level 2). Each level was run in duplicate twice each day for a minimum of 20 days at each of the three test sites using the control material (XN CHECK BF). The results were analyzed in accordance with the CLSI EP05-A3 approved guideline.

Device: XN-L XN CHECK BF, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC-BF	Level 1	240	0.09	0.004	4.9	0	0	0.002	2.82	0.002	2.59	0.005	6.22
x 10^3/µL	Level 2	240	0.33	0.01	2.89	0	0	0.005	1.47	0.007	1.99	0.013	3.8
RBC-BF	Level 1	240	0.03	0.001	4.01	0	0	0	0.76	0	0.71	0.001	4.14
x 10^6/µL	Level 2	240	0.08	0.001	1.78	0	0.27	0.001	0.89	0.001	1.2	0.002	2.34
MN	Level 1	240	0.03	0.002	7.94	0	0	0.001	3.86	0	0.91	0.003	8.87

Device: XN-L XN CHECK BF, Combined Sites													
All Sites Combined				Within - Run		Between - Run		Between - Day		Between - Site		Total	
Measurand	Control level	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
x $10^3/\mu L$	Level 2	240	0.11	0.005	4.56	0.001	1.28	0	0	0.003	2.36	0.006	5.29
MN	Level 1	240	33.9	2.09	6.18	0.59	1.74	0.52	1.53	0.29	0.85	2.25	6.65
%	Level 2	240	34.7	1.24	3.57	0.33	0.96	0.2	0.58	0	0	1.3	3.74
PMN	Level 1	240	0.06	0.003	5.81	0	0	0.001	2.54	0.002	3.2	0.004	7.11
x $10^3/\mu L$	Level 2	240	0.21	0.007	3.47	0	0	0.004	1.94	0.004	1.75	0.009	4.35
PMN	Level 1	240	66.1	2.09	3.16	0.59	0.89	0.52	0.78	0.29	0.44	2.25	3.41
%	Level 2	240	65.3	1.24	1.9	0.33	0.51	0.2	0.31	0	0	1.3	1.99
TC-BF	Level 1	240	0.1	0	4.9	0	0	0	2.82	0	2.59	0.01	6.22
x $10^3/\mu L$	Level 2	240	0.3	0.01	2.89	0	0	0	1.47	0.01	1.99	0.01	3.8

c. Linearity:

Whole Blood

Linearity studies were performed in accordance with the CLSI EP06-A approved guideline. Serial dilutions of known high concentrations control material which spanned the full measuring range of all direct measured parameters (WBC, RBC, HGB, PLT, HCT, RET) and related measurements, were aspirated in the Whole Blood Automated Sampling Mode at three clinical sites. Each serial dilution was run in duplicate.

Polynomial regression analyses for the first, second and third-order polynomials were performed for each evaluated parameter.

Measurand	Site	r2	r	Slope	Intercept	Range
WBC ($10^3/\mu L$)	1	1.0000	1.0000	1.003	-0.1014	(0.00, 562.17)
	2	1.0000	1.0000	1.004	-0.2100	(0.00, 561.92)
	3	1.0000	1.0000	1.001	-0.1640	(0.00, 570.55)
RBC ($10^6/\mu L$)	1	1.0000	1.0000	1.000	0.0070	(0.00, 8.65)
	2	0.9998	0.9999	0.991	0.0128	(0.00, 8.70)
	3	0.9999	0.9999	1.007	-0.0085	(0.00, 8.70)
HGB (g/dL)	1	1.0000	1.0000	1.001	0.0034	(0.0, 26.1)
	2	1.0000	1.0000	1.000	0.0115	(0.0, 26.4)
	3	1.0000	1.0000	1.002	0.0011	(0.0, 26.2)
HCT (%)	1	0.9999	1.0000	0.9952	0.0512	(0.0, 73.3)
	2	0.9999	1.0000	1.0038	-0.0663	(0.0, 75.3)
	3	0.9999	1.0000	1.0000	0.0200	(0.0, 75.4)
PLT ($10^3/\mu L$	1	1.0000	1.0000	1.001	-1.2170	(0, 6113)
	2	0.9999	0.9999	1.006	-3.8119	(0, 5804)

Measurand	Site	r2	r	Slope	Intercept	Range
	3	0.9999	1.0000	1.003	-5.7788	(0, 5905)
RET (%)	1	0.9986	0.9993	0.9846	0.2031	(0.00, 35.21)
	2	0.9996	0.9998	1.0036	-0.0666	(0.00, 37.62)
	3	0.9997	0.9999	0.9999	-0.0522	(0.00, 37.55)

Body Fluids

Linearity studies were performed at 3 clinical sites using serial dilutions of known high concentrations of body fluid samples which spanned the full measuring range of the WBC-BF, RBC-BF, and TC-BF parameters in accordance with the CLSI EP06-A approved guideline Section 5.5.5. Pleural, peritoneal, and synovial fluids were collected in K2EDTA anticoagulant. All samples were aspirated in the Body Fluid Mode. Each serial dilution was run in duplicate.

Body Type	Measurand	Site	r^2	r	Slope	Intercept	Range
CSF	WBC-BF ($10^3/\mu L$)	1	1.0000	1.0000	0.996	0.003	(0.000, 15.180)
		2	1.0000	1.0000	0.997	0.003	(0.004, 13.725)
		3	1.0000	1.0000	1.003	-0.003	(0.002, 11.718)
	RBC-BF ($10^6/\mu L$)	1	0.9999	1.0000	0.994	0.002	(0.000, 5.893)
		2	1.0000	1.0000	0.998	0.000	(0.001, 5.297)
		3	1.0000	1.0000	1.004	-0.001	(0.001, 4.955)
	TC-BF# ($10^3/\mu L$)	1	1.0000	1.0000	0.996	0.003	(0.000, 15.187)
		2	1.0000	1.0000	0.997	0.003	(0.004, 13.753)
		3	1.0000	1.0000	1.003	-0.003	(0.002, 11.749)
Peritoneal	WBC-BF ($10^3/\mu L$)	1	0.9997	0.9999	1.010	-0.011	(0.000, 10.490)
		2	1.0000	1.0000	0.999	-0.001	(0.001, 17.155)
		3	0.9998	0.9999	0.991	0.007	(0.002, 9.105)
	RBC-BF ($10^6/\mu L$)	1	1.0000	1.0000	1.001	-0.001	(0.000, 5.872)
		2	1.0000	1.0000	0.997	0.001	(0.001, 5.201)
		3	0.9999	1.0000	1.002	-0.001	(0.002, 5.830)
	TC-BF# ($10^3/\mu L$)	1	0.9997	0.9999	1.010	-0.011	(0.000, 10.496)
		2	1.0000	1.0000	0.999	-0.001	(0.002, 17.158)
		3	0.9998	0.9999	0.991	0.007	(0.002, 9.110)
Pleural	WBC-BF ($10^3/\mu L$)	1	0.9999	0.9999	0.991	0.003	(0.000, 14.636)
		2	1.0000	1.0000	0.998	0.006	(0.002, 15.457)
		3	0.9999	0.9999	1.006	0.003	(0.002, 8.916)
	RBC-BF ($10^6/\mu L$)	1	1.0000	1.0000	1.000	-0.002	(0.000, 6.078)
		2	1.0000	1.0000	1.001	-0.002	(0.001, 5.510)
		3	0.9999	1.0000	0.998	0.002	(0.001, 3.251)
	TC-BF# ($10^3/\mu L$)	1	0.9999	1.0000	0.992	0.003	(0.000, 15.058)

Body Type	Measurand	Site	r^2	r	Slope	Intercept	Range
		2	1.0000	1.0000	0.998	0.006	(0.002, 15.478)
		3	0.9999	0.9999	1.006	0.003	(0.002, 8.917)
Synovial	WBC-BF (10^3/µL)	1	1.0000	1.0000	1.000	-0.006	(0.000, 19.615)
		2	0.9999	1.0000	0.994	0.005	(0.002, 10.833)
		3	1.0000	1.0000	1.000	0.001	(0.002, 10.547)
	RBC-BF (10^6/µL)	1	1.0000	1.0000	0.996	0.001	(0.000, 5.308)
		2	0.9999	1.0000	1.008	-0.002	(0.001, 5.298)
		3	1.0000	1.0000	1.002	0.001	(0.001, 5.746)
	TC-BF# (10^3/µL)	1	1.0000	1.0000	1.000	-0.006	(0.000, 19.626)
		2	0.9999	1.0000	0.994	0.005	(0.002, 10.837)
		3	1.0000	1.0000	1.000	0.001	(0.002, 10.562)

d. Carryover:

Whole Blood

Carryover was evaluated by assaying whole blood K2EDTA samples with high WBC, RBC, HGB, HCT, and PLT counts three consecutive times (H1, H2, H3) followed immediately by testing samples with low target values around medical decision levels consecutively three times (L1, L2, L3) in accordance with CLSI H26-A2. Three sets of carryover sequences were run for each measurand in the Whole Blood Mode at three clinical sites.

Carryover formula:

$$\frac{(L1 - L3)}{(H3 - L3)} \times 100\%$$

Where: L1 is the first low sample analyzed;

L3 is the last low sample analyzed;

H3 is the last high sample analyzed.

The carryover results for the XN-L analyzer met the manufacturer's specifications.

Body Fluid

The carryover protocol was run in the Body Fluid Mode by assaying residual body fluid samples with a high WBC-BF, TC-BF and RBC-BF count three consecutive times (H1, H2, H3) followed immediately by testing samples with low target values around medical decision levels consecutively three times (L1, L2, L3) in accordance with the CLSI H26-A2 approved guideline. Three sets of carryover sequences were

run for each type of carryover test in the Body Fluid Mode at three clinical sites. Pleural, peritoneal, and synovial fluids were collected in K2EDTA anticoagulant. Carryover effect was calculated for each measurand using the formula from the ICSH Expert Panel on Cytometry, "Guidelines for the Evaluation of Blood Cell Analyzers", as demonstrated in the table below.

$$\frac{(L1 - L3)}{(H3 - L3)} \times 100\%$$

Where: L1 is the first low sample analyzed;

L3 is the last low sample analyzed;

H3 is the last high sample analyzed.

The carryover results for the XN-L analyzer met the manufacturer's specifications.

e. *Interfering Substances*:

Interfering substances studies for Bilirubin C, Bilirubin F, Hemolytic Hemoglobin, Lipemia (intralipid) and Chyle interferents were performed on the XN-L. A total of 6 whole blood K2EDTA samples were collected from three donors each. All tubes were centrifuged and 150 µL of plasma removed from each. Each interferent was diluted to (0%, 20%, 40%, 60%, 80%, and 100%) and then 150 µL of each dilution was added to the centrifuged tubes (from a single donor). The tubes were mixed and measured three consecutive times for WBC, RBC, HGB, HCT, PLT, RET%/#, IRF, and RET-He on the XN-L.

There was no significant Bilirubin F interference up to a concentration of 40.0 mg/dL for WBC, RBC, HGB, HCT, RET%/#, and RET-He parameters, up to a concentration of 8.0 mg/dL for PLT parameter, and up to a concentration of 24.0 mg/dL for IRF parameter.

There was no significant Bilirubin C interference up to a concentration of 42.2 mg/dL for WBC, RBC, HGB, HCT, PLT, RET%/#, and RET-He parameters. A significant Bilirubin C interference was observed at a concentration of 8.4 mg/dL for IRF parameter.

There was no significant hemolysis interference up to a concentration of 1018.0 mg/dL for WBC, RBC, HCT, PLT, RET%/#, and RET-He parameters, up to a concentration of 203.6 mg/dL for HGB parameter. A significant hemolysis interference was observed at a concentration of 203.6 mg/dL for IRF parameter.

There was no significant intralipid interference up to a concentration of 2.00 g/dL for WBC, RBC, HCT, RET%/#, IRF, and RET-He parameters, up to a concentration of

1.00 g/dL for PLT and 1.00 g/dL IRF parameters, and up to a concentration of 0.2 g/dL for HGB parameter.

There was no significant chyle interference up to a concentration of 2800 FTU for WBC, RBC, HGB, HCT, RET%/#, IRF, and RET-He parameters and up to a concentration of 1680 FTU for PLT parameter.

2. Other Supportive Instrument Performance Data Not Covered Above:

A. Sample Stability

Whole Blood

The sample stability study for the XN-L analyzer was performed at one site using normal and abnormal venous whole blood K2EDTA samples obtained within 8 hours of sample collection. Aliquots were prepared for each specimen and stored at room temperature (18–26°C) and refrigerated temperature (2–8°C). Refrigerated samples were allowed to come to room temperature before testing. All samples were hand mixed by gentle inversion 10 times and analyzed in duplicate at baseline (time zero), 8, 24 and 26 hours at room temperature and baseline (time zero), 6, 12, 13, 48 and 50 hours at refrigerated temperature in the Manual Whole Blood Mode.

Acceptance criteria for each parameter was established for defined time intervals at each storage condition as the difference between the recovery of the measurand at defined time points and time point zero (T0). The acceptance criteria were met for each claimed storage condition: 24 hours for whole blood samples stored at room temperature (18–26°C) and 48 hours for whole blood samples stored at refrigerated temperature (2–8°C).

Body Fluids

Body fluid short term stability was evaluated using a minimum of two different residual CSF, pleural, peritoneal, and synovial fluids at one site. Pleural, peritoneal, and synovial fluids were collected in K2EDTA anticoagulant and run in singlet in the Body Fluid Mode. Each sample was carefully mixed by gentle hand inversion at least 10 times before analyzing on the XN-L analyzer and tested at baseline (0 time), 1 hour , 2 hour, 4 hours, 6 hours, and 8 hours at room temperature (20–25°C).

Per established literature, body fluid samples should be stored at room temperature and analyzed within 1 hour of collection.

B. Verification of Reference Intervals

Whole Blood – Adult

Verification of adult reference intervals testing was performed on the XN-L analyzer to demonstrate comparability of whole blood reference ranges for an adult population (>21 years) to the ranges established for a predicate device. Prospective samples for adults were collected in K2EDTA anticoagulant from a total of 80 donors (40 males; 40 females) at one site. All specimens were analyzed in singlet in the Automated Whole Blood Sampling Mode. The upper and lower limits of the established reference ranges

were compared to the study results. References were also provided to substantiate the reference intervals verified in the study.

Whole Blood – Pediatric

A literature reference interval verification study was performed for the pediatric population. A total of 136 samples were collected from apparently healthy pediatric patients in pediatric subcategories (≥ 2 to <12 (49 samples)) and ≥ 12 to <21 (87 samples)) to support the Intended Use. All samples were collected in K2EDTA anticoagulant and analyzed in singlet in the Automated Whole Blood Sampling Mode. The upper and lower limits of the published reference ranges were compared to the study results.

Body Fluids

A verification study was conducted using a minimum of 20 normal CSF and 20 normal Synovial fluids to verify normal reference ranges cited from published literature (Kjeldsberg's Body Fluids, Third Edition (1993)[1]). Reference intervals for other body fluid types have not been established. According to Kjeldsberg (1993), reference intervals for RBC count are not applicable in body fluid, and therefore, no reference interval for RBC has been established.

C. Matrix Studies

1. *Whole Blood Anticoagulant Comparison (K2EDTA vs. K3EDTA)*

   Anticoagulant comparison studies were performed to evaluate comparability between K2EDTA and K3EDTA anticoagulated whole blood samples on the XN-L analyzer. A total of 40 paired (K2 and K3EDTA) whole blood samples were used for this study. The samples were run in singlet in the Whole Blood Automated Sampling Mode and the K2EDTA sample results were compared to the corresponding results of the K3EDTA sample for the same donor.

2. *Whole Blood Venous to Capillary Comparison*

   A comparison study was performed to demonstrate comparability between venous whole blood samples and capillary whole blood samples on the XN-L analyzer. A total of 40 paired whole blood venous samples and capillary samples (K2EDTA) were used for this study. Venous whole blood samples were run in the Whole Blood Automated Sampling Mode (Normal Tube Position) and capillary whole blood samples in the Whole Blood Manual Mode (Micro-collection Tube Position) in singlet on the XN-L analyzer. The venous whole blood sample results were compared to the corresponding results of the capillary sample for the same donor.

D. Bridging Studies

[1] 1Kjeldsberg C. and Knight J. *Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids.* 3rd ed. Chicago, IL: ASCP Press. 1993.

1. *Whole Blood K2EDTA Tube to Micro-tube Comparison*

   A total of 51 residual K2EDTA (4 mL tubes) anticoagulated whole blood samples with analyte concentrations representative of normal patient samples, patient samples across medical decision levels, and the analytical measuring range, to the extent possible, were used to determine the presence or absence of matrix effect between K2EDTA normal tubes and micro collection tubes on the XN-L analyzer. K2EDTA normal tubes were run in singlet in the Manual Mode Normal Tube Position and within 2 hours of analysis, the samples were transferred to micro collection tubes (without additive) and analyzed in the Manual Mode Micro-collection Tube Position.

2. *Whole Blood Pre-dilute Mode Normal Tube to Micro-tube Comparison*

   A total of 40 residual K2EDTA (4 mL tubes) anticoagulated whole blood samples were used to determine the equivalency between the Pre-dilute Mode Normal Tube Position and the Pre-dilute Mode Micro-collection tube position. Pre-diluted samples (1:7) were prepared for each sample by dispensing 420 µL of the analyzer diluent into plain top tubes (4 mL tubes) then adding 70 µL of whole blood and mixing 10 times by gentle inversion. The plain top 4 mL tubes were run in singlet in the Pre-dilute Mode normal tube position. Immediately following, the samples were mixed 10 times then transferred to micro-collection tubes (without additive) and analyzed in the Pre-dilute Mode micro-collection tube position (Cap Off). Results in the mode are automatically multiplied by 7 before results are displayed, therefore no additional calculation is required.

3. Low WBC (LWBC) Mode Normal Tube Position to Micro Tube Comparison- Whole Blood
   A total of 40 residual K2EDTA anticoagulated whole blood samples and 20 LWBC samples were used to determine the equivalency between the LWBC Mode Normal tube position and the LWBC Mode micro-collection tube position. The original K2EDTA sample tube was hand mixed by gentle inversion 10 times and run in the singlet in the LWBC Mode Normal tube position on the XN-L analyzer. Immediately following, the samples were mixed 10 times then transferred to micro-collection tubes (without additive) and analyzed in the LWBC Mode micro-collection tube position (Cap Off).

E. Determination of limit of Blank, lower limits of detection and quantitation:

Whole Blood

Limit of Blank

The Limit of Blank (LoB) for WBC, RBC, HGB, HCT and PLT was determined using the system diluent as a blank sample. A total of 12 repeated measurements using one blank sample were tested on four XN-L analyzers over a period of 5 days for a total of 60 measurements per analyzer (12 reps x 1 sample x 4 analyzers x 5

days) for each parameter. Testing was conducted in the Whole Blood Manual Mode in accordance with CLSI EP17-A2. The results obtained from all four analyzers were used to calculate the Mean, SD, and LoB for each parameter. The results of the LoB are included in the table below.

Limit of Detection and Quantitation

The Limit of Detection (LoD) for the WBC, RBC, HGB, HCT and PLT parameters were determined using venous whole blood K2EDTA anticoagulated samples diluted with system diluent to create four low concentration samples not exceeding three times the manufacturer's claimed limit of blank for WBC, RBC, HGB, HCT, PLT, for a predicate device which is 0.10, 0.02, 0.1, 10, 0.001 and 0.003, respectively. Samples were tested in replicates of five measurements over three days using two XN-L analyzers for a total of 60 measurements for each parameter. Samples were mixed by gentle hand inversion 10 times and analyzed in Whole Blood Mode in accordance with CLSI EP17-A2. The measurements obtained from all analyzers were used to calculate the Mean, SD, and LoD for each parameter. The results of the LoD and LoQ are included in the following table below.

[Whole Blood] mode				
Parameters	**Limit of blank (LoB)**	**Limit of detection (LoD)**	**Limit of quantitation (LoQ)**	**Units**
WBC[*1]	0.00	0.01	0.03	x 10^3/µL
RBC	0.00	0.00	0.00	x 10^6/µL
HGB	0.0	0.0	0.0	g/dL
PLT	0	0	1	x 10^3/µL
HCT	0.0	0.0	0.0	%

*1 The white blood cell count measured from the WDF channel. (CBC+DIFF mode)

Body Fluids

Limit of Blank

The LoB for WBC-BF, RBC-BF and TC-BF was determined using the system diluent as a blank sample. A total of 12 repeated measurements using one blank sample were tested on four XN-L analyzers over a period of 5 days for a total of 60 measurements per analyzer (12 reps x 1 sample x 4 analyzers x 5 days) for each parameter. Testing was conducted in the Body Fluid Mode by one operator in accordance with the CLSI EP17-A2 approved guideline. The results obtained from all four analyzers were used to calculate the Mean, SD, and LoB for each parameter. The results of the LoB are included in the table below.

Limits of Detection and Quantitation

The LoD for the WBC-BF, RBC-BF and TC-BF parameters were determined using

body fluid samples diluted with system diluent to create four low concentration samples not exceeding three times the manufacture's claimed limit of blank for BC-BF/TC-BF and RBC-BF for a predicate device which is 0.10, 0.02, 0.1, 10, 0.001 and 0.003, respectively. Samples were tested in replicates of five measurements over 3 days using two XN-L analyzers for a total of 60 measurements for each parameter. Samples were mixed by gentle hand inversion 10 times and analyzed in the Body Fluid Manual Mode and tested in accordance with CLSI EP17-A2. The measurements obtained from all analyzers were used to calculate the Mean, SD, and LoD for each parameter. The results of the LoD and LoQ are included in the following table below.

[Body Fluid] Mode				
Parameters	**Limit of blank (LoB)**	**Limit of detection (LoD)**	**Limit of quantitation (LoQ)**	**Units**
WBC-BF	0.000	0.002	0.004	x $10^3/\mu L$
RBC-BF	0.000	0.000	0.001	x $10^3/\mu L$
TC-BF#	0.000	0.002	0.004	x $10^3/\mu L$

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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