510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K160586

B. Purpose for Submission:

Clearance of a new device

C. Measurand:

Assayed parameters: RBC (10^6/µL), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT (10^3/µL), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC (10^3/µL), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# (10^3/µL), LYMPH# (10^3/µL), MONO# (10^3/µL), EO# (10^3/µL), BASO# (10^3/µL), IG# (10^3/µL), RET# (10^6/µL), RET%, IRF%, RET-He (pg).

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

XN-L CHECK™

G. Regulatory Information:

1. Regulation section:

   21 CFR § 864.8625, Hematology quality control mixture

2. Classification:

   Class II

3. Product code:

   JPK, Mixture, hematology quality control

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   XN-L CHECK™ is used for control and calibration verification of Sysmex XN-L analyzers. It is not, however, intended for actual calibration of this analyzer.

   Assayed parameters include: RBC (10^6/µL), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT (10^3/µL), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC (10^3/µL), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# (10^3/µL), LYMPH# (10^3/µL),MONO# (10^3/µL), EO# (10^3/µL), BASO# (10^3/µL), IG# (10^3/µL), RET# (10^6/µL), RET%, IRF%, RET-He (pg).

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Sysmex XL-N analyzer

I. Device Description:

XN-L CHECK™ is an in-vitro diagnostic, three level (Levels 1, 2, and 3) hematology control 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. The product is packaged in polypropylene plastic vials with screw caps with a 3 mL fill. The vials will be packaged in four-welled vacuum formed clamshell container with the Instructions for Use (IFU) / assay sheet. Product storage temperature is 2 – 8° C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   XN-CHECK™

2. Predicate 510(k) number(s):

3. Comparison with predicate:

Similarities		
Item	Device: XN-L CHECK™	Predicate: XN-CHECK™
Storage Conditions	2 – 8˚C	Same

Differences		
Item	Device: XN-L CHECK™	Predicate: XN-CHECK™
Intended Use	XN-L CHECK™ is used for control and calibration verification of Sysmex XN-L analyzers. It is not, however, intended for actual calibration of this analyzer. Assayed parameters include: RBC (106/μL), HGB (g/dL), HCT (%), MCV (fL), MCH (pg), MCHC (g/dL), PLT (10^3/μL), RDW-SD (fL), RDW-CV (%), MPV (fL), WBC (10^3/μL), NEUT (%), LYMPH (%), MONO (%), EO (%), BASO (%), IG (%), NEUT# (10^3/μL), LYMPH# (10^3/μL), MONO# (10^3/μL), EO# (10^3/μL), BASO# (10^3/μL), IG# (10^3/μL), RET# (10^6/μL), RET%, IRF%, RET-He (pg). Product is a control for XN-L analyzer. The following measurands are not available on XN-L CHECK or the XN-L analyzer: IPF(#) IPF(%) NRBC#(10^3/μL) NRBC%(/100WBC)	XN CHECK™ is used for control and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21, XL-N) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters include: RBC(10^6/μL), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT(103/μL), PLT-F(103/μL), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC(103/μL), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#(10^3/μL), LYMPH#(10^3/μL), MONO#(10^3/μL), EO#(10^3/μL), BASO#(103/μL), IG#(10^3/μL), IPF(%), IPF # (10^3/μL) RET#(10^6/μL), RET%, IRF%, RET-HE(pg), NRBC#(10^3/μL), NRBC% (/100 WBC)
Open Vial Stability	15 days	7 days
Closed Vial Stability	100 days	84 days
Reagents	XN-L CHECK™ 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™ 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.

K. Standard/Guidance Document Referenced (if applicable):

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, October 2010

CLSI EP5-A3 Methods, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Third Edition.

L. Test Principle:

Tri-level XN-L CHECK™ was designed to evaluate the accuracy and precision of the Sysmex XN-L instrument. XN-L CHECK™ is for in-vitro diagnostic use only by laboratory professionals.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision:

i. Multi-site reproducibility study: The multisite precision study was conducted at three separate sites, Streck, Sysmex-Buffalo Grove, and Sysmex-Mundelein, with three different operators. Three separately manufactured lots of XN-L CHECK were tested on each XN-L analyzer. Each site was instructed to run each lot and level of control for 5 days with 2 runs per day and 3 replicates per run. The final dataset resulted in a total of 90 measurements per lot and control level (level 1, level 2, and level 3). The total reproducibility estimates for each parameter for each lot include the repeatability (within-run), between-run, between-day, and between-site precision estimates. Total reproducibility numbers for each parameter are used to calculate the acceptable range for each parameter of control. The results of the precision studies met the performance specifications for each XN-L CHECK Hematology Control level.

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6106)												
			Repeatability		Between Run		Between Day		Within-Lab Precision		Reproducibility	
Sample	Control level	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	level 1	2.62	0.06	2.2	0.02	0.7	0.02	0.8	0.06	2.5	0.08	3.0
	level 2	6.85	0.10	1.4	0.01	0.2	0.05	0.7	0.11	1.6	0.16	2.4
	level 3	16.34	0.17	1.0	0.06	0.4	0.04	0.2	0.18	1.1	0.40	2.4
NEUT%	level 1	45.7	1.0	2.1	0.0	0.0	0.0	0.0	1.0	2.1	1.0	2.2
	level 2	48.3	0.7	1.4	0.3	0.6	0.0	0.0	0.7	1.5	0.8	1.6
	level 3	52.5	0.7	1.4	0.0	0.0	0.3	0.5	0.8	1.5	0.8	1.4

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6106)												
			Repeatability		Between Run		Between Day		Within-Lab Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
LYMPH%	level 1	27.8	0.9	3.3	0.6	2.1	0.4	1.4	1.1	4.1	1.2	4.2
	level 2	24.4	0.5	2.0	0.4	1.7	0.3	1.4	0.7	3.0	0.8	3.3
	level 3	19.2	0.4	2.3	0.0	0.1	0.3	1.6	0.5	2.8	0.5	2.8
MONO%	level 1	8.7	0.6	7.2	0.6	6.6	0.5	6.2	1.0	11.5	1.1	12.1
	level 2	8.5	0.4	5.2	0.2	2.0	0.5	5.5	0.7	7.8	0.7	8.1
	level 3	8.1	0.2	2.7	0.3	3.6	0.4	4.9	0.5	6.7	0.5	6.8
EO%	level 1	11.8	0.6	5.1	0.0	0.0	0.1	1.1	0.6	5.2	0.6	5.1
	level 2	12.6	0.5	4.3	0.1	1.0	0.0	0.0	0.6	4.5	0.6	4.6
	level 3	13.4	0.5	3.7	0.0	0.0	0.3	1.9	0.6	4.2	0.6	4.3
BASO%	level 1	5.9	0.3	5.7	0.0	0.0	0.1	1.8	0.4	6.0	0.4	6.0
	level 2	6.2	0.3	4.7	0.0	0.0	0.0	0.0	0.3	4.4	0.3	4.4
	level 3	6.7	0.3	3.8	0.1	1.4	0.0	0.3	0.3	4.0	0.3	4.0
NEUT#	level 1	1.20	0.04	2.9	0.02	1.3	0.01	1.0	0.04	3.3	0.04	3.6
	level 2	3.31	0.07	2.1	0.03	0.9	0.02	0.5	0.08	2.3	0.09	2.6
	level 3	8.58	0.14	1.7	0.00	0.0	0.04	0.5	0.15	1.7	0.25	2.9
LYMPH#	level 1	0.73	0.03	3.9	0.01	1.7	0.01	1.8	0.03	4.6	0.04	5.0
	level 2	1.67	0.04	2.6	0.03	1.5	0.03	1.6	0.06	3.4	0.07	4.1
	level 3	3.13	0.08	2.6	0.01	0.4	0.04	1.4	0.09	3.0	0.12	3.7
MONO#	level 1	0.23	0.02	7.9	0.01	6.2	0.01	5.9	0.03	11.7	0.03	12.6
	level 2	0.58	0.03	4.9	0.01	2.4	0.03	5.6	0.05	7.8	0.05	8.5
	level 3	1.33	0.04	2.7	0.05	3.5	0.07	5.0	0.09	6.7	0.10	7.4
EO#	level 1	0.31	0.02	5.4	0.00	1.1	0.01	2.0	0.02	5.8	0.02	5.9
	level 2	0.86	0.04	4.4	0.00	0.5	0.01	1.2	0.04	4.6	0.05	5.4
	level 3	2.20	0.08	3.7	0.01	0.4	0.04	2.0	0.09	4.3	0.09	4.3
BASO#	level 1	0.16	0.01	6.5	0.00	1.5	0.00	0.0	0.01	6.7	0.01	7.1
	level 2	0.42	0.02	5.0	0.00	0.0	0.00	0.0	0.02	4.6	0.02	5.0
	level 3	1.10	0.04	4.0	0.01	1.2	0.00	0.4	0.05	4.2	0.05	5.0
IG%	level 1	12.8	0.8	6.2	0.0	0.0	0.1	0.9	0.8	6.3	0.8	6.4
	level 2	13.2	0.8	6.3	0.3	2.4	0.0	0.0	0.9	6.7	0.9	6.8
	level 3	14.5	0.8	5.7	0.3	1.9	0.6	4.3	1.1	7.4	1.1	7.4
IG#	level 1	0.33	0.02	6.1	0.01	1.7	0.01	1.8	0.02	6.6	0.02	7.2
	level 2	0.91	0.06	6.4	0.03	3.0	0.01	1.1	0.06	7.1	0.07	7.3
	level 3	2.37	0.13	5.6	0.06	2.3	0.10	4.4	0.18	7.5	0.18	7.6
RBC	level 1	2.24	0.01	0.6	0.01	0.3	0.01	0.3	0.02	0.8	0.03	1.2
	level 2	4.15	0.02	0.5	0.02	0.4	0.00	0.1	0.03	0.7	0.04	1.0
	level 3	5.20	0.03	0.5	0.01	0.2	0.02	0.3	0.03	0.6	0.04	0.9
HGB	level 1	5.9	0.0	0.7	0.0	0.5	0.0	0.4	0.1	1.0	0.1	1.5

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6106)												
			Repeatability		Between Run		Between Day		Within-Lab Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
	level 2	12.5	0.1	0.4	0.0	0.1	0.0	0.1	0.1	0.5	0.1	1.0
	level 3	16.9	0.1	0.4	0.0	0.2	0.0	0.1	0.1	0.5	0.2	1.0
HCT%	level 1	17.2	0.1	0.6	0.1	0.5	0.1	0.8	0.2	1.1	0.6	3.6
	level 2	35.4	0.2	0.5	0.1	0.4	0.2	0.5	0.3	0.8	1.1	3.0
	level 3	46.4	0.2	0.5	0.2	0.4	0.2	0.4	0.3	0.7	1.4	3.0
MCV	level 1	76.8	0.2	0.3	0.3	0.4	0.4	0.6	0.6	0.7	2.0	2.6
	level 2	85.2	0.1	0.2	0.5	0.6	0.4	0.5	0.7	0.8	1.9	2.3
	level 3	89.2	0.2	0.2	0.4	0.4	0.4	0.5	0.6	0.7	2.2	2.5
MCH	level 1	26.2	0.3	1.1	0.0	0.0	0.1	0.5	0.3	1.2	0.3	1.2
	level 2	30.2	0.2	0.7	0.2	0.6	0.0	0.1	0.3	0.9	0.3	0.9
	level 3	32.4	0.2	0.6	0.1	0.3	0.1	0.4	0.2	0.8	0.3	0.8
MCHC	level 1	34.0	0.3	1.0	0.1	0.4	0.3	0.8	0.5	1.4	0.9	2.6
	level 2	35.4	0.2	0.7	0.2	0.5	0.1	0.4	0.3	0.9	0.8	2.3
	level 3	36.4	0.2	0.6	0.2	0.4	0.2	0.4	0.3	0.8	0.9	2.4
RDW-SD	level 1	47.8	0.3	0.5	0.7	1.4	0.3	0.5	0.8	1.6	1.4	2.8
	level 2	47.0	0.2	0.5	0.5	1.1	0.2	0.5	0.6	1.3	1.1	2.3
	level 3	46.3	0.3	0.6	0.1	0.3	0.2	0.4	0.3	0.8	1.2	2.7
RDW-CV	level 1	17.2	0.1	0.5	0.2	1.3	0.2	0.9	0.3	1.7	0.3	1.8
	level 2	15.1	0.1	0.5	0.1	0.4	0.0	0.3	0.1	0.6	0.1	0.8
	level 3	14.3	0.1	0.6	0.1	0.7	0.0	0.3	0.1	0.9	0.2	1.1
PLT	level 1	58	2	4.3	2	2.7	1	2.4	3	5.6	3	5.9
	level 2	224	6	2.5	4	1.9	3	1.4	8	3.4	9	4.2
	level 3	561	7	1.3	3	0.5	4	0.6	9	1.5	20	3.6
MPV	level 1	10.7	0.3	2.4	0.2	1.8	0.1	0.8	0.3	3.1	0.5	4.3
	level 2	10.1	0.1	1.2	0.1	0.9	0.1	0.8	0.2	1.7	0.2	2.3
	level 3	9.8	0.1	0.6	0.1	0.6	0.0	0.4	0.1	0.9	0.2	1.8
RET(%)	level 1	5.40	0.15	2.8	0.15	2.8	0.13	2.4	0.25	4.6	0.34	6.3
	level 2	2.03	0.05	2.7	0.02	1.0	0.02	0.8	0.06	3.0	0.13	6.3
	level 3	0.79	0.04	4.5	0.02	2.2	0.01	1.9	0.04	5.3	0.05	6.6
RET#	level 1	0.1208	0.0033	2.7	0.0031	2.5	0.0031	2.6	0.0055	4.5	0.0084	6.9
	level 2	0.0845	0.0022	2.6	0.0010	1.2	0.0007	0.8	0.0025	3.0	0.0057	6.7
	level 3	0.0410	0.0017	4.2	0.0012	2.8	0.0009	2.2	0.0023	5.6	0.0028	6.8
IRF(%)	level 1	16.8	1.3	7.6	0.8	4.9	1.2	7.1	1.9	11.5	1.9	11.5
	level 2	19.6	1.4	7.3	1.6	8.1	1.5	7.5	2.6	13.3	2.7	13.6
	level 3	17.2	1.8	10.3	1.9	11.2	1.2	7.1	2.9	16.8	3.1	17.8
RET-He	level 1	22.3	0.1	0.5	0.2	0.9	0.2	0.7	0.3	1.2	0.9	4.1
	level 2	23.1	0.2	0.8	0.1	0.5	0.1	0.5	0.2	1.1	0.9	3.9

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6106)												
			Repeatability		Between Run		Between Day		Within-Lab Precision		Reproducibility	
Sample	Control level	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
	level 3	24.0	0.3	1.4	0.1	0.6	0.0	0.0	0.4	1.5	1.0	4.3

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6134)												
			Repeatability		Between Run		Between Day		Between-Site Precision		Reproducibility	
Sample	Control level	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	level 1	2.50	0.06	2.4	0.01	0.5	0.02	0.8	0.06	2.6	0.08	3.1
	level 2	6.94	0.11	1.5	0.00	0.0	0.06	0.8	0.12	1.7	0.19	2.7
	level 3	16.54	0.18	1.1	0.04	0.2	0.02	0.1	0.18	1.1	0.41	2.5
NEUT%	level 1	44.9	1.0	2.2	0.5	1.1	0.1	0.3	1.1	2.5	1.1	2.5
	level 2	47.7	0.7	1.6	0.0	0.0	0.2	0.4	0.8	1.6	0.8	1.6
	level 3	52.1	0.7	1.3	0.1	0.2	0.1	0.2	0.7	1.3	0.7	1.3
LYMPH%	level 1	28.7	1.2	4.1	0.3	1.0	0.6	1.9	1.3	4.6	1.3	4.7
	level 2	24.6	0.6	2.4	0.0	0.2	0.2	0.7	0.6	2.5	0.7	3.0
	level 3	18.9	0.3	1.7	0.1	0.5	0.2	0.9	0.4	1.9	0.4	2.1
MONO%	level 1	8.8	0.7	7.7	0.4	4.8	0.2	1.7	0.8	9.2	0.8	9.6
	level 2	9.0	0.4	4.2	0.1	0.9	0.1	0.9	0.4	4.4	0.4	4.6
	level 3	8.5	0.3	3.2	0.2	2.0	0.1	1.2	0.3	3.9	0.3	4.0
EO%	level 1	11.7	0.5	4.4	0.1	0.7	0.0	0.0	0.5	4.4	0.5	4.4
	level 2	12.5	0.5	4.1	0.1	1.1	0.1	0.9	0.5	4.4	0.5	4.4
	level 3	13.7	0.5	3.5	0.2	1.6	0.2	1.2	0.6	4.0	0.6	4.1
BASO%	level 1	5.9	0.4	6.6	0.0	0.0	0.0	0.0	0.4	6.6	0.4	6.6
	level 2	6.3	0.3	5.1	0.0	0.5	0.1	1.4	0.3	5.4	0.3	5.4
	level 3	6.9	0.3	4.7	0.0	0.0	0.0	0.0	0.3	4.7	0.3	4.8
NEUT#	level 1	1.12	0.04	3.3	0.01	0.6	0.00	0.0	0.04	3.4	0.04	3.9
	level 2	3.31	0.07	2.1	0.00	0.0	0.03	1.0	0.08	2.3	0.11	3.2
	level 3	8.61	0.13	1.5	0.01	0.1	0.00	0.0	0.13	1.5	0.22	2.6
LYMPH#	level 1	0.72	0.04	5.0	0.00	0.0	0.02	2.3	0.04	5.5	0.04	5.6
	level 2	1.71	0.04	2.5	0.00	0.0	0.01	0.4	0.04	2.6	0.06	3.7
	level 3	3.13	0.06	2.0	0.03	0.9	0.03	1.0	0.08	2.4	0.10	3.3
MONO#	level 1	0.22	0.02	7.6	0.01	5.6	0.00	2.2	0.02	9.7	0.02	10.2
	level 2	0.62	0.03	4.6	0.01	1.3	0.01	1.6	0.03	5.0	0.04	5.7
	level 3	1.40	0.05	3.3	0.02	1.7	0.02	1.4	0.06	4.0	0.06	4.6
EO#	level 1	0.29	0.01	4.5	0.00	1.0	0.00	0.0	0.01	4.6	0.01	4.8
	level 2	0.87	0.04	4.7	0.00	0.0	0.01	1.6	0.04	5.0	0.04	5.2

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6134)												
			Repeatability		Between Run		Between Day		Between-Site Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
	level 3	2.27	0.08	3.7	0.04	1.6	0.03	1.3	0.10	4.3	0.11	5.0
BASO#	level 1	0.15	0.01	7.2	0.00	1.2	0.00	0.0	0.01	7.3	0.01	7.5
	level 2	0.44	0.02	5.3	0.00	0.7	0.01	1.6	0.02	5.6	0.03	5.9
	level 3	1.14	0.06	4.9	0.00	0.0	0.00	0.0	0.06	4.9	0.07	5.9
IG%	level 1	12.3	0.8	6.2	0.0	0.0	0.0	0.0	0.8	6.2	0.8	6.2
	level 2	13.2	0.8	6.1	0.4	3.1	0.0	0.0	0.9	6.9	0.9	6.9
	level 3	14.6	0.8	5.6	0.3	1.9	0.4	2.4	0.9	6.4	0.9	6.5
IG#	level 1	0.31	0.02	6.4	0.00	0.0	0.00	0.6	0.02	6.4	0.02	6.7
	level 2	0.91	0.06	6.6	0.03	3.0	0.00	0.0	0.07	7.2	0.07	7.6
	level 3	2.41	0.13	5.6	0.05	2.0	0.07	2.7	0.16	6.6	0.16	6.6
RBC	level 1	2.27	0.02	0.7	0.01	0.3	0.00	0.1	0.02	0.8	0.02	1.0
	level 2	4.20	0.02	0.5	0.02	0.5	0.04	0.9	0.05	1.1	0.06	1.4
	level 3	5.12	0.02	0.4	0.01	0.2	0.01	0.2	0.03	0.5	0.04	0.8
HGB	level 1	6.1	0.0	0.7	0.0	0.1	0.0	0.0	0.0	0.7	0.1	1.3
	level 2	12.4	0.0	0.4	0.0	0.0	0.1	0.9	0.1	1.0	0.2	1.4
	level 3	16.9	0.1	0.4	0.0	0.1	0.0	0.3	0.1	0.5	0.2	1.0
HCT%	level 1	17.4	0.1	0.8	0.0	0.2	0.1	0.6	0.2	1.0	0.6	3.2
	level 2	35.0	0.2	0.5	0.2	0.5	0.4	1.2	0.5	1.4	1.2	3.5
	level 3	46.1	0.2	0.4	0.2	0.4	0.3	0.6	0.4	0.8	1.4	3.1
MCV	level 1	76.8	0.2	0.2	0.2	0.2	0.5	0.6	0.5	0.7	2.0	2.6
	level 2	83.2	0.1	0.2	0.3	0.3	0.4	0.5	0.5	0.6	2.1	2.5
	level 3	90.1	0.1	0.1	0.3	0.3	0.5	0.5	0.6	0.6	2.2	2.5
MCH	level 1	26.8	0.3	0.9	0.1	0.5	0.0	0.0	0.3	1.1	0.3	1.2
	level 2	29.5	0.2	0.6	0.1	0.4	0.0	0.0	0.2	0.7	0.2	0.8
	level 3	32.9	0.2	0.6	0.1	0.2	0.1	0.2	0.2	0.7	0.3	0.8
MCHC	level 1	34.9	0.3	0.9	0.2	0.5	0.2	0.6	0.4	1.2	0.8	2.4
	level 2	35.4	0.2	0.6	0.2	0.5	0.2	0.5	0.3	0.9	0.8	2.3
	level 3	36.6	0.2	0.6	0.1	0.3	0.2	0.5	0.3	0.9	0.9	2.4
RDW-SD	level 1	45.4	0.3	0.7	0.2	0.4	0.3	0.6	0.4	1.0	1.0	2.3
	level 2	45.0	0.3	0.6	0.1	0.2	0.3	0.6	0.4	0.8	1.1	2.4
	level 3	45.9	0.3	0.5	0.1	0.2	0.3	0.6	0.4	0.8	1.4	3.0
RDW-CV	level 1	16.2	0.1	0.4	0.1	0.3	0.1	0.6	0.1	0.8	0.1	0.9
	level 2	14.9	0.1	0.4	0.0	0.1	0.0	0.2	0.1	0.5	0.1	0.6
	level 3	13.8	0.1	0.5	0.0	0.0	0.1	0.4	0.1	0.6	0.1	1.0
PLT	level 1	58	2	4.3	1	2.4	1	2.3	3	5.4	3	5.4
	level 2	225	5	2.2	4	1.7	3	1.2	7	3.0	8	3.6
	level 3	542	7	1.2	6	1.1	5	1.0	10	1.9	21	3.8

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6134)												
			Repeatability		Between Run		Between Day		Between-Site Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
MPV	level 1	10.3	0.2	2.3	0.0	0.0	0.0	0.3	0.2	2.3	0.3	2.8
	level 2	9.7	0.1	1.1	0.1	0.7	0.1	0.6	0.1	1.4	0.2	1.8
	level 3	9.4	0.1	0.6	0.0	0.4	0.0	0.3	0.1	0.8	0.1	1.2
RET(%)	level 1	4.29	0.13	3.1	0.04	0.9	0.08	1.9	0.16	3.8	0.56	12.9
	level 2	1.96	0.06	3.1	0.00	0.0	0.02	1.0	0.06	3.2	0.17	8.4
	level 3	0.72	0.04	5.5	0.01	1.4	0.01	1.5	0.04	5.9	0.06	8.9
RET#	level 1	0.0973	0.0032	3.2	0.0000	0.0	0.0020	2.0	0.0037	3.8	0.0131	13.5
	level 2	0.0824	0.0024	3.0	0.0000	0.0	0.0015	1.8	0.0029	3.5	0.0077	9.4
	level 3	0.0368	0.0020	5.4	0.0006	1.6	0.0006	1.6	0.0022	5.9	0.0033	9.1
IRF(%)	level 1	10.8	0.9	8.1	0.5	4.2	0.9	8.5	1.4	12.5	1.5	13.5
	level 2	11.7	1.0	8.4	0.5	4.4	0.7	5.7	1.3	11.1	1.5	13.2
	level 3	9.7	1.1	11.3	0.3	2.7	1.1	11.3	1.6	16.2	1.8	18.7
RET-He	level 1	23.2	0.1	0.5	0.0	0.1	0.1	0.6	0.2	0.7	1.0	4.2
	level 2	23.9	0.2	0.6	0.0	0.0	0.1	0.4	0.2	0.8	1.0	4.3
	level 3	25.0	0.3	1.2	0.1	0.5	0.1	0.6	0.4	1.4	1.1	4.4

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6190)												
			Repeatability		Between Run		Between Day		Between-Site Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
WBC	level 1	2.50	0.06	2.3	0.00	0.0	0.01	0.5	0.06	2.3	0.10	3.9
	level 2	6.79	0.09	1.4	0.00	0.0	0.05	0.7	0.10	1.5	0.20	2.9
	level 3	16.13	0.13	0.8	0.04	0.2	0.10	0.6	0.17	1.1	0.45	2.8
NEUT%	level 1	45.8	1.1	2.4	0.0	0.0	0.0	0.0	1.1	2.4	1.1	2.4
	level 2	47.7	0.9	1.9	0.0	0.0	0.0	0.0	0.9	1.9	0.9	1.9
	level 3	52.4	0.8	1.5	0.2	0.3	0.0	0.1	0.8	1.5	0.8	1.5
LYMPH%	level 1	28.4	1.1	3.8	0.6	2.0	0.0	0.0	1.2	4.3	1.2	4.3
	level 2	25.0	0.6	2.6	0.0	0.0	0.0	0.0	0.6	2.6	0.7	2.6
	level 3	19.0	0.4	2.2	0.1	0.7	0.2	0.8	0.5	2.4	0.5	2.5
MONO%	level 1	8.2	0.6	7.8	0.3	4.0	0.2	2.1	0.7	9.0	0.7	9.0
	level 2	8.5	0.4	4.6	0.1	1.6	0.0	0.0	0.4	4.9	0.4	4.9
	level 3	8.4	0.2	2.8	0.0	0.0	0.1	0.7	0.2	2.9	0.2	2.9
EO%	level 1	11.6	0.7	5.9	0.0	0.0	0.2	1.6	0.7	6.1	0.7	6.1
	level 2	12.5	0.7	5.2	0.2	1.4	0.0	0.0	0.7	5.4	0.7	5.4
	level 3	13.3	0.7	5.3	0.1	0.8	0.3	2.0	0.8	5.7	0.8	5.7

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6190)												
			Repeatability		Between Run		Between Day		Between-Site Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
BASO%	level 1	6.0	0.4	6.7	0.1	2.3	0.0	0.0	0.4	7.1	0.4	7.1
	level 2	6.3	0.3	4.9	0.0	0.6	0.1	1.9	0.3	5.3	0.3	5.3
	level 3	7.0	0.4	5.5	0.1	1.0	0.0	0.0	0.4	5.6	0.4	5.6
NEUT#	level 1	1.15	0.04	3.3	0.00	0.0	0.00	0.3	0.04	3.3	0.05	4.7
	level 2	3.24	0.08	2.4	0.00	0.0	0.00	0.0	0.08	2.4	0.11	3.5
	level 3	8.45	0.15	1.8	0.05	0.6	0.06	0.7	0.17	2.0	0.27	3.2
LYMPH#	level 1	0.71	0.03	4.5	0.01	1.5	0.00	0.0	0.03	4.8	0.04	5.9
	level 2	1.70	0.05	2.9	0.01	0.6	0.00	0.0	0.05	2.9	0.07	4.1
	level 3	3.06	0.07	2.4	0.02	0.7	0.04	1.4	0.09	2.9	0.13	4.3
MONO#	level 1	0.21	0.02	8.4	0.01	3.9	0.00	2.4	0.02	9.6	0.02	9.6
	level 2	0.58	0.03	4.8	0.01	1.7	0.01	1.0	0.03	5.2	0.03	5.5
	level 3	1.35	0.04	2.9	0.00	0.0	0.01	0.8	0.04	3.0	0.05	4.0
EO#	level 1	0.29	0.02	5.8	0.00	0.0	0.00	1.1	0.02	5.9	0.02	6.3
	level 2	0.85	0.04	5.3	0.00	0.4	0.00	0.0	0.05	5.3	0.05	5.9
	level 3	2.14	0.11	5.1	0.02	1.0	0.04	1.8	0.12	5.5	0.12	5.7
BASO#	level 1	0.15	0.01	7.0	0.00	1.3	0.00	0.0	0.01	7.1	0.01	7.6
	level 2	0.43	0.02	5.4	0.00	0.0	0.01	1.9	0.02	5.7	0.02	5.7
	level 3	1.13	0.06	5.7	0.01	0.6	0.00	0.0	0.07	5.8	0.07	6.2
IG%	level 1	12.8	1.0	8.1	0.0	0.0	0.0	0.0	1.0	8.1	1.0	8.1
	level 2	13.6	0.8	6.1	0.2	1.6	0.0	0.0	0.9	6.3	0.9	6.3
	level 3	14.7	1.0	6.5	0.4	3.0	0.1	0.8	1.1	7.2	1.1	7.4
IG#	level 1	0.32	0.03	8.6	0.00	0.0	0.00	0.0	0.03	8.6	0.03	9.3
	level 2	0.92	0.06	6.4	0.02	1.7	0.01	1.1	0.06	6.7	0.06	6.8
	level 3	2.37	0.16	6.7	0.07	2.8	0.01	0.3	0.17	7.2	0.18	7.4
RBC	level 1	2.20	0.02	0.8	0.00	0.1	0.00	0.2	0.02	0.9	0.02	1.1
	level 2	4.38	0.02	0.5	0.01	0.2	0.02	0.4	0.03	0.6	0.04	0.9
	level 3	5.17	0.03	0.5	0.01	0.2	0.01	0.1	0.03	0.6	0.05	1.0
HGB	level 1	5.6	0.0	0.7	0.0	0.0	0.0	0.2	0.0	0.7	0.1	1.5
	level 2	12.5	0.1	0.5	0.0	0.0	0.0	0.3	0.1	0.6	0.1	1.1
	level 3	16.5	0.1	0.4	0.0	0.1	0.0	0.2	0.1	0.5	0.2	1.1
HCT%	level 1	15.8	0.1	0.8	0.1	0.3	0.1	0.4	0.1	0.9	0.5	3.1
	level 2	34.5	0.2	0.4	0.1	0.4	0.2	0.5	0.3	0.8	1.0	3.0
	level 3	44.8	0.2	0.5	0.2	0.4	0.2	0.4	0.3	0.7	1.4	3.1
MCV	level 1	71.9	0.2	0.3	0.1	0.2	0.2	0.3	0.3	0.4	1.6	2.2
	level 2	78.8	0.1	0.2	0.2	0.2	0.1	0.2	0.3	0.3	1.8	2.3
	level 3	86.5	0.1	0.2	0.4	0.4	0.2	0.2	0.4	0.5	2.0	2.3
MCH	level 1	25.4	0.2	0.9	0.0	0.1	0.1	0.2	0.2	1.0	0.3	1.1

MULTI-SITE PRECISION												
XN-L CHECK (Lot 6190)												
			Repeatability		Between Run		Between Day		Between-Site Precision		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
	level 2	28.4	0.2	0.6	0.1	0.3	0.1	0.2	0.2	0.7	0.2	0.8
	level 3	31.8	0.2	0.6	0.0	0.0	0.1	0.2	0.2	0.6	0.2	0.6
MCHC	level 1	35.3	0.3	0.9	0.1	0.4	0.2	0.5	0.4	1.1	0.7	2.0
	level 2	36.1	0.2	0.6	0.2	0.5	0.1	0.3	0.3	0.8	0.8	2.1
	level 3	36.8	0.2	0.6	0.1	0.3	0.1	0.3	0.3	0.7	0.8	2.2
RDW-SD	level 1	46.1	0.3	0.7	0.0	0.0	0.1	0.1	0.3	0.7	0.6	1.3
	level 2	48.7	0.3	0.6	0.0	0.0	0.1	0.2	0.3	0.6	0.8	1.5
	level 3	44.5	0.3	0.6	0.2	0.5	0.1	0.2	0.3	0.8	0.9	2.1
RDW-CV	level 1	17.4	0.1	0.6	0.0	0.0	0.1	0.4	0.1	0.7	0.3	1.6
	level 2	16.8	0.1	0.6	0.0	0.1	0.0	0.3	0.1	0.6	0.3	1.5
	level 3	14.1	0.1	0.4	0.1	0.5	0.0	0.2	0.1	0.7	0.2	1.2
PLT	level 1	58	2	3.9	0	0.0	1	1.7	2	4.3	3	5.5
	level 2	218	5	2.2	2	1.0	1	0.5	5	2.4	9	4.2
	level 3	541	8	1.4	1	0.1	3	0.6	8	1.5	22	4.1
MPV	level 1	10.2	0.2	2.2	0.0	0.0	0.0	0.0	0.2	2.2	0.2	2.2
	level 2	9.9	0.1	1.3	0.0	0.0	0.0	0.1	0.1	1.3	0.1	1.5
	level 3	9.6	0.1	0.6	0.0	0.0	0.0	0.3	0.1	0.6	0.1	1.1
RET(%)	level 1	5.07	0.13	2.5	0.06	1.2	0.08	1.6	0.16	3.2	0.42	8.3
	level 2	2.15	0.06	3.0	0.03	1.5	0.02	1.0	0.07	3.4	0.18	8.6
	level 3	0.85	0.04	5.2	0.02	2.4	0.01	0.8	0.05	5.7	0.09	10.4
RET#	level 1	0.1114	0.0032	2.8	0.0013	1.2	0.0020	1.8	0.0040	3.6	0.0100	9.0
	level 2	0.0943	0.0030	3.2	0.0013	1.4	0.0009	1.0	0.0034	3.6	0.0086	9.1
	level 3	0.0438	0.0022	5.1	0.0012	2.6	0.0006	1.3	0.0026	5.9	0.0047	10.8
IRF(%)	level 1	16.1	1.5	9.1	0.1	0.5	1.1	6.8	1.8	11.4	2.5	15.7
	level 2	11.3	1.1	9.8	0.4	4.0	0.4	3.6	1.3	11.2	2.0	17.9
	level 3	10.8	1.4	12.9	0.2	1.5	0.4	4.0	1.5	13.6	2.4	21.8
RET-He	level 1	22.7	0.1	0.5	0.0	0.0	0.1	0.4	0.1	0.7	0.9	3.8
	level 2	23.4	0.2	0.9	0.0	0.2	0.1	0.4	0.2	1.0	1.0	4.1
	level 3	25.1	0.4	1.4	0.1	0.3	0.1	0.4	0.4	1.5	1.1	4.2

ii. Single site (internal) precision: Performance data provided by the closed-vial stability study was used to support the internal precision study. In this study, performance of three lots of XN-L CHECK was evaluated at one site, on one instrument, for 21 non-consecutive days, two vials per day, and two replicates per vial. Running two vials per day was determined to be an appropriate substitute for two runs per day. The internal precision for each lot of XN-L CHECK was consistent across lots for each assayed parameter. Total variability estimates (within-lab precision) included repeatability (within-run), between-vial, and

between-day.

SINGLE SITE PRECISION ANALYSIS (POOLED RESULTS)												
XN-L CHECK												
			Repeatability		Between Run		Between Day		Between Lot		Reproducibility	
Sample	Control level	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	level 1	2.42	0.06	2.6	0.01	0.3	0.01	0.4	0.07	2.8	0.06	2.7
	level 2	6.73	0.10	1.5	0.02	0.3	0.02	0.3	0.10	1.5	0.11	1.6
	level 3	15.35	0.18	1.2	0.05	0.3	0.05	0.3	0.10	0.6	0.19	1.3
NEUT%	level 1	45.3	1.1	2.3	0.2	0.5	0.2	0.4	0.0	0.0	1.1	2.4
	level 2	48.5	0.8	1.6	0.3	0.6	0.2	0.4	0.3	0.7	0.8	1.7
	level 3	52.5	0.6	1.2	0.1	0.1	0.2	0.5	0.3	0.7	0.7	1.3
LYMPH%	level 1	28.9	1.1	3.8	0.4	1.3	0.0	0.0	0.3	1.0	1.2	4.1
	level 2	24.3	0.5	2.3	0.2	0.9	0.2	0.7	0.3	1.3	0.6	2.5
	level 3	19.6	0.4	1.9	0.2	0.9	0.1	0.6	0.3	1.6	0.4	2.2
MONO%	level 1	7.8	0.6	7.5	0.2	2.1	0.2	2.3	0.5	5.8	0.6	8.1
	level 2	7.9	0.4	4.9	0.1	1.0	0.1	1.6	0.5	6.1	0.4	5.2
	level 3	7.2	0.3	3.9	0.0	0.0	0.1	1.4	0.5	6.7	0.3	4.2
EO%	level 1	11.8	0.5	3.9	0.2	1.8	0.0	0.0	0.1	0.7	0.5	4.4
	level 2	12.7	0.5	4.0	0.1	0.9	0.2	1.2	0.2	1.5	0.5	4.3
	level 3	13.7	0.5	3.7	0.2	1.2	0.2	1.2	0.2	1.4	0.6	4.1
BASO%	level 1	6.1	0.4	7.3	0.1	1.4	0.1	2.1	0.0	0.6	0.5	7.7
	level 2	6.5	0.3	5.2	0.1	1.8	0.0	0.7	0.1	0.8	0.4	5.4
	level 3	7.0	0.3	4.9	0.0	0.2	0.0	0.7	0.1	0.8	0.3	4.9
NEUT#	level 1	1.10	0.04	3.8	0.00	0.0	0.01	0.5	0.03	2.6	0.04	3.8
	level 2	3.27	0.07	2.2	0.01	0.3	0.02	0.6	0.02	0.7	0.08	2.3
	level 3	8.05	0.14	1.8	0.02	0.3	0.05	0.6	0.02	0.3	0.15	1.9
LYMPH#	level 1	0.70	0.03	4.1	0.01	2.1	0.00	0.0	0.01	1.8	0.03	4.6
	level 2	1.64	0.04	2.7	0.02	1.0	0.01	0.8	0.04	2.6	0.05	3.0
	level 3	3.01	0.07	2.4	0.03	0.8	0.02	0.7	0.00	0.0	0.08	2.6
MONO#	level 1	0.19	0.01	7.7	0.00	2.0	0.00	2.6	0.02	8.6	0.02	8.4
	level 2	0.53	0.03	5.0	0.01	1.2	0.01	1.5	0.04	7.3	0.03	5.3
	level 3	1.11	0.04	3.8	0.01	1.1	0.01	1.1	0.04	3.5	0.05	4.1
EO#	level 1	0.29	0.01	5.0	0.00	0.9	0.00	0.8	0.01	1.9	0.01	5.1
	level 2	0.86	0.04	4.4	0.00	0.4	0.01	1.3	0.00	0.0	0.04	4.6
	level 3	2.11	0.08	3.9	0.02	1.2	0.02	1.1	0.00	0.0	0.09	4.1
BASO#	level 1	0.15	0.01	7.9	0.00	2.3	0.00	2.5	0.00	2.3	0.01	8.6
	level 2	0.44	0.02	5.2	0.01	2.3	0.00	0.6	0.00	0.4	0.03	5.7
	level 3	1.07	0.05	4.9	0.00	0.0	0.01	1.0	0.00	0.2	0.05	5.0
IG%	level 1	12.3	0.7	5.6	0.2	1.9	0.2	1.3	0.0	0.3	0.7	6.0
	level 2	13.1	0.6	4.7	0.1	0.5	0.1	0.8	0.0	0.3	0.6	4.8

SINGLE SITE PRECISION ANALYSIS (POOLED RESULTS)												
XN-L CHECK												
			Repeatability		Between Run		Between Day		Between Lot		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
	level 3	14.2	0.6	4.1	0.1	0.9	0.3	1.8	0.0	0.3	0.6	4.6
IG#	level 1	0.30	0.02	6.0	0.00	1.3	0.00	1.3	0.01	3.2	0.02	6.2
	level 2	0.88	0.04	5.0	0.00	0.5	0.01	0.8	0.01	1.0	0.05	5.1
	level 3	2.17	0.09	4.3	0.02	0.8	0.04	1.8	0.01	0.4	0.10	4.8
RBC	level 1	2.24	0.02	0.8	0.00	0.0	0.02	0.7	0.01	0.5	0.02	1.0
	level 2	4.23	0.02	0.5	0.00	0.0	0.03	0.7	0.05	1.1	0.04	0.8
	level 3	5.18	0.02	0.5	0.01	0.1	0.03	0.5	0.05	0.9	0.04	0.7
HGB	level 1	6.0	0.0	0.6	0.0	0.3	0.0	0.5	0.1	1.6	0.0	0.8
	level 2	12.6	0.0	0.4	0.0	0.1	0.1	0.4	0.3	2.6	0.1	0.6
	level 3	16.8	0.0	0.3	0.0	0.1	0.1	0.3	0.3	1.9	0.1	0.4
HCT%	level 1	17.4	0.1	0.8	0.0	0.0	0.1	0.8	0.4	2.1	0.2	1.1
	level 2	35.7	0.2	0.5	0.0	0.0	0.3	0.9	0.5	1.5	0.4	1.0
	level 3	46.3	0.2	0.4	0.0	0.1	0.4	0.9	0.5	1.2	0.5	1.0
MCV	level 1	77.7	0.2	0.3	0.1	0.1	0.7	0.9	1.5	1.9	0.8	1.0
	level 2	84.4	0.1	0.2	0.0	0.0	0.8	0.9	1.9	2.2	0.8	1.0
	level 3	89.5	0.1	0.2	0.0	0.0	0.9	1.0	1.9	2.1	0.9	1.0
MCH	level 1	26.6	0.3	0.9	0.1	0.2	0.2	0.8	0.3	1.2	0.3	1.2
	level 2	29.7	0.2	0.6	0.1	0.2	0.2	0.7	0.9	2.9	0.3	1.0
	level 3	32.4	0.2	0.5	0.1	0.2	0.2	0.6	0.9	2.7	0.3	0.9
MCHC	level 1	34.2	0.3	0.9	0.1	0.2	0.3	0.8	0.3	0.8	0.4	1.3
	level 2	35.2	0.2	0.6	0.1	0.2	0.3	1.0	0.4	1.2	0.4	1.2
	level 3	36.2	0.2	0.5	0.1	0.2	0.3	0.9	0.4	1.2	0.4	1.1
RDW-SD	level 1	45.1	0.3	0.7	0.2	0.4	0.4	0.9	0.2	0.4	0.5	1.2
	level 2	44.5	0.3	0.7	0.0	0.0	0.7	1.5	0.6	1.2	0.8	1.7
	level 3	46.4	0.3	0.6	0.1	0.2	0.9	1.9	0.6	1.2	0.9	2.0
RDW-CV	level 1	16.0	0.1	0.6	0.0	0.1	0.1	0.7	0.2	1.3	0.1	0.9
	level 2	14.6	0.1	0.6	0.0	0.2	0.1	0.8	0.4	2.9	0.2	1.0
	level 3	14.2	0.1	0.5	0.0	0.0	0.2	1.2	0.4	3.0	0.2	1.3
PLT	level 1	56	2	3.8	1	1.5	1	1.6	0	0.7	2	4.4
	level 2	223	4	1.7	2	0.8	2	0.7	2	0.8	5	2.0
	level 3	527	7	1.3	2	0.4	3	0.5	2	0.4	8	1.4
MPV	level 1	10.9	0.3	2.3	0.1	0.7	0.0	0.4	0.3	2.3	0.3	2.5
	level 2	10.4	0.1	1.0	0.0	0.1	0.0	0.2	0.2	2.3	0.1	1.0
	level 3	10.2	0.1	0.6	0.0	0.1	0.0	0.5	0.2	2.3	0.1	0.8
RET(%)	level 1	6.30	0.16	2.5	0.07	1.1	0.06	0.9	0.09	1.4	0.18	2.9
	level 2	2.71	0.08	2.8	0.03	1.1	0.04	1.6	0.08	3.1	0.09	3.4
	level 3	1.05	0.05	4.7	0.00	0.4	0.04	3.4	0.08	8.1	0.06	5.8

SINGLE SITE PRECISION ANALYSIS (POOLED RESULTS)												
XN-L CHECK												
			Repeatability		Between Run		Between Day		Between Lot		Reproducibility	
Sample	**Control level**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
RET#	level 1	0.1412	0.0039	2.7	0.0016	1.2	0.0018	1.3	0.0027	1.9	0.0046	3.2
	level 2	0.1144	0.0034	2.9	0.0014	1.2	0.0023	2.0	0.0045	3.9	0.0043	3.8
	level 3	0.0542	0.0025	4.6	0.0000	0.0	0.0021	3.9	0.0045	8.3	0.0033	6.0
IRF(%)	level 1	19.9	1.4	6.9	0.9	4.3	1.4	6.8	0.7	3.8	2.1	10.6
	level 2	23.7	1.5	6.2	0.0	0.0	1.5	6.3	1.1	4.8	2.1	8.9
	level 3	20.4	1.6	7.9	0.4	2.1	0.8	4.1	1.1	5.6	1.9	9.1
RET-He	level 1	22.0	0.1	0.5	0.0	0.0	0.5	2.5	0.1	0.4	0.6	2.5
	level 2	22.7	0.2	0.7	0.1	0.2	0.6	2.4	0.1	0.6	0.6	2.6
	level 3	24.2	0.3	1.2	0.2	0.8	0.7	2.9	0.1	0.6	0.8	3.3

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Value Assignments

Value assignment for XN-L CHECK™ was based on data collected across three XN-L instruments conducted at three separate sites, Streck, Sysmex-Buffalo Grove, and Sysmex-Mundelein, with three different operators. Three separately manufactured lots of XN-L CHECK were tested on each analyzer. Each site was instructed to run each lot and level of control for 5 days with 2 runs per day and 3 replicates per run. The final dataset resulted in a total of 90 measurements per lot and control level (level 1, level 2, and level 3). Standard deviation from the multi-site total reproducibility was used to determine the range of each parameter of XN-L CHECK. Future control lots will be value assigned at one site by a minimum of one operator. Five repeat measurements are taken from two separate vials of control material and assayed in a single run on each of 2 days. The average of the 20 individual results will be used for value assignment.

<u>Open-Vial Stability</u>

Open-vial stability testing was performed real-time for the 15-day open-vial stability claim throughout the stated product life. One vial of control per level from each lot was analyzed four times over a period of 16 days (n=16). Testing was conducted at day 0, 7, 15, and 16. Day 0 is the baseline value that was observed on the first day of the study. Day 16 was collected one day after the stated open vial stability claim to ensure that the open vial stability claim was fully encompassed. Throughout the

collection of the open-vial stability data each vial of control was stored in accordance with the Instructions for Use. Each vial was stored between 2° to 8° C and removed from the refrigerator for testing. After testing, the vial was returned to the refrigerator until the next testing event.

Stability performance of each control lot was assessed in terms of parameter drift over time (for each parameter), as described in CLSI EP25-A – "Evaluation of Stability of In Vitro Diagnostic Agents; Approved Guideline". Values associated with each parameter, for each lot, and at each time point were within the acceptable value range, supportive of a 15-day open vial stability claim.

Closed-Vial Stability

The 100-day closed-vial stability claim was verified on the XN-L instrument with three lots of control (5015, 5046, and 5074). Two vials of control per level from each reference lot were used at each testing interval for this study. A minimum of four data points were collected at each testing event over the 100-day closed-vial stability claim. Data was collected internally with one operator. Day 0 is the baseline value that was observed on the first day of the study. One data point was collected after the stated closed-vial stability claim to ensure that the closed vial stability claim was fully encompassed.

Results of the closed-vial stability testing were assessed for each lot and level in terms of measurand drift as stated in CLSI EP25-A, Evaluation of Stability of *In Vitro* Diagnostics Reagents, Approved Guideline.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable

   b. Clinical specificity:

   Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not applicable

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   The end-user is instructed to refer to the product assay sheet accompanying the instructions for use.

N. Proposed Labeling:

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

O. Conclusion:

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