

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k141964

B. Purpose for Submission:

Clearance of new device-Addition of a new parameter - IPF# ($10^3/\mu\text{L}$)

C. Measurand:

Assayed parameters: RBC($10^6/\mu\text{L}$), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT($10^3/\mu\text{L}$), PLT-F($10^3/\mu\text{L}$), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC($10^3/\mu\text{L}$), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#($10^3/\mu\text{L}$), LYMPH#($10^3/\mu\text{L}$), MONO# ($10^3/\mu\text{L}$), EO#($10^3/\mu\text{L}$), BASO#($10^3/\mu\text{L}$), IG#($10^3/\mu\text{L}$), IPF(%), RET#($10^6/\mu\text{L}$), RET%, IRF%, RET-HE(pg), NRBC#($10^3/\mu\text{L}$), and NRBC% (/100 WBC), and IPF# ($10^3/\mu\text{L}$).

D. Type of Test:

Quantitative

E. Applicant:

Streck Inc.

F. Proprietary and Established Names:

XN-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 CHECK is used for control and calibration verification of Sysmex XN (XN-10, XN-11, XN-20, XN-21) analyzers. It is not, however, intended for actual calibration of these analyzers.

Assayed parameters include: RBC($10^6/\mu\text{L}$), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT($10^3/\mu\text{L}$), PLT-F($10^3/\mu\text{L}$), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC($10^3/\mu\text{L}$), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#($10^3/\mu\text{L}$), LYMPH#($10^3/\mu\text{L}$), MONO# ($10^3/\mu\text{L}$), EO#($10^3/\mu\text{L}$), BASO#($10^3/\mu\text{L}$), IG#($10^3/\mu\text{L}$), IPF(%), RET#($10^6/\mu\text{L}$), RET%, IRF%, IPF# ($10^3/\mu\text{L}$), RET-HE(pg), NRBC#($10^3/\mu\text{L}$), and NRBC% (/100 WBC).

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 XN series (XN-10, XN-11, XN-20, XN-21) analyzers

I. Device Description:

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. The control includes three levels (i.e., low, medium and high) which are packaged separately in polypropylene plastic vials with screw caps containing 3mL. The vials will be packaged in (4) wellled vacuum formed clamshell container with the Instructions for Use (IFU) / assay sheet. The product must be stored at 2 - 8°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Streck XN CHECK™

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

k120742

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Control Levels	3 levels	same
Open-vial stability	7 days	same
Closed-vial stability	84 days	same
Storage conditions	2-8°C	same
Reagents	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.	same

Differences		
Item	Device	Predicate
Intended Use	XN CHECK is used for control and calibration verification of Sysmex XN (XN-10, XN-20) analyzers. It is not, however, intended for actual calibration of these analyzers. Assayed parameters include: RBC($10^6/\mu\text{L}$), HGB(g/dL), HCT(%), MCV(fL), MCH(pg), MCHC(g/dL), PLT($10^3/\mu\text{L}$), PLT-F($10^3/\mu\text{L}$), RDW-SD(fL), RDW-CV(%), MPV(fL), WBC($10^3/\mu\text{L}$), NEUT(%), LYMPH (%), MONO(%), EO(%), BASO(%), IG(%), NEUT#($10^3/\mu\text{L}$), LYMPH#($10^3/\mu\text{L}$), MONO#($10^3/\mu\text{L}$), EO#($10^3/\mu\text{L}$), BASO#($10^3/\mu\text{L}$), IG#($10^3/\mu\text{L}$), IPF(%), RET#($10^6/\mu\text{L}$), RET%, IRF%, RET-HE(pg), NRBC#($10^3/\mu\text{L}$), and NRBC% (/100 WBC)	Only for Sysmex XN-10 and XN-20 models Assayed parameter IPF# ($10^3/\mu\text{L}$) not available

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

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

CLSI EP5-A2 Methods, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

L. Test Principle:

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

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Data were collected at 3 sites (two internal and at one external site) across 3 different Sysmex XN-20 and XN-21 models analyzers, throughout the product dating claim using 3 separately manufactured lots numbers (3280, 3322, 3336) of XN-CHECK™ controls. Studies were conducted for each lot at all three sites; all sites are within the U.S. Control materials were shipped, stored, mixed, and handled in accordance with the instruction for use. Acceptance criteria were based on compilation of the CV% for each measurand across all models over multiple sites. Results collected across the three separately manufactured lots of XN CHECK™ demonstrate consistent recovery across multiple instruments, at multiple sites and were within the parameter specific assay assignment ranges set forth for each measurand as shown in the cumulative summary by instrument series in the tables below.

Sysmex XN-20 Model Level 1											
Measurand (%CV)											
	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PLT-F%	RDW	RDW-CV
Lot 3280	3.07	1.51	4.07	1.92	3.55	4.06	5.6	2.1	1.2	0.89	3.07
Lot 3322	1.78	3.75	1.46	4.25	1.68	4.06	4.1	6.1	2.2	1.19	1.06
Lot 3336	2.31	2.78	1.71	4.39	2.16	3.01	4.3	6.4	2.2	1.77	0.77
CV% Acceptance Criteria	5.0	5.0	5.0	5.0	5.0	5.0	5.0	10.0	5.0	5.0	5.0

Sysmex XN-20 Model Level 2											
Measurand (%CV)											
	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PLT-F%	RDW	RDW-CV
Lot 3280	1.81	3.23	0.78	3.93	1.80	3.75	4.16	4.0	5.5	1.66	1.14
Lot 3322	1.23	4.01	0.81	4.39	1.57	4.54	4.65	5.5	3.7	1.36	1.03
Lot 3336	1.6	2.87	1.11	4.28	1.94	3.02	4.27	3.1	4.0	1.52	1.09
CV% Acceptance Criteria	5.0	5.0	5.0	5.0	5.0	5.0	5.0	10.0	5.0	5.0	5.0

Sysmex XN-20 Model Level 3											
Measurand (%CV)											
	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PLT-F%	RDW	RDW-CV
Lot 3280	1.30	2.58	0.81	3.13	1.67	2.99	3.21	3.7	2.7	1.42	1.22
Lot 3322	1.20	4.28	0.77	4.51	1.50	4.90	4.86	6.5	1.9	1.36	1.07
Lot 3336	0.92	2.55	0.98	3.81	1.73	2.61	3.71	3.3	1.7	1.30	1.69
CV% Acceptance Criteria	5.0	5.0	5.0	5.0	5.0	5.0	5.0	10.0	5.0	5.0	5.0

Sysmex XN-20 Model Level 1											
Measurand (%CV)											
	MPV	NEUT#	LYMPH#	MONO#	EO#	BASO#	IG#	NEUT%	NEUT%	LYMPH %	MONO %
Lot 3280	4.31	3.52	4.63	8.25	7.42	4.49	4.16	2.66	2.66	8.08	4.31
Lot 3322	5.48	3.41	5.04	10.8	7.58	3.46	3.74	2.83	2.83	10.52	5.48
Lot 3336	3.72	3.19	5.77	12.1	7.34	4.53	3.79	2.57	2.57	11.91	3.72
CV% Acceptance Criteria	5.0	15.0	10.0	15.0	10.0	10.0	10.0	5.0	5.0	10.0	15.0

Sysmex XN-20 Model Level 2											
Measurand (%CV)											
	MPV	NEUT#	LYMPH#	MONO#	EO#	BASO#	IG#	NEUT%	NEUT%	LYMPH %	MONO %
Lot 3280	2.18	2.62	3.99	8.89	7.7	3.04	3.19	1.96	1.96	8.35	2.18
Lot 3322	2.63	2.73	4.62	9.13	7.7	2.87	2.79	2.32	2.32	9.37	2.63
Lot 3336	1.95	2.95	4.20	9.86	7.9	3.14	3.59	2.24	2.24	9.52	1.95
CV% Acceptance Criteria	5.0	5.0	10.0	15.0	10.0	5.0	5.0	5.0	5.0	10.0	15.0

Sysmex XN-20 Model Level 3											
Measurand (%CV)											
	MPV	NEUT#	LYMPH#	MONO#	EO#	BASO#	IG#	NEUT%	NEUT%	LYMPH %	MONO %
Lot 3280	1.99	2.47	7.75	12.26	6.82	2.35	3.46	1.9	1.9	12.4	1.99
Lot 3322	2.23	2.43	6.37	11.51	6.47	3.07	3.12	1.9	1.9	11.5	2.23
Lot 3336	1.96	2.18	5.69	11.43	7.61	2.21	2.93	1.8	1.8	11.6	1.96
CV% Acceptance Criteria	5.0	5.0	10.0	15.0	10.0	5.0	5.0	5.0	5.0	10.0	15.0

Sysmex XN-20 Model Level 1											
Measurand (%CV)											
	EO%	BASO%	IG%	NRBC#	NRBC %	RET#	RET%	IRF	RET-He	IPF%	IPF#
Lot 3280	7.22	3.62	3.37	10.44	10.11	9.08	6.91	11.00	1.84	2.94	3.74
Lot 3322	7.41	3.26	3.24	9.20	9.62	8.68	6.70	19.44	8.35	2.83	3.52
Lot 3336	7.02	3.71	3.46	8.38	8.61	6.28	5.49	16.37	5.15	2.19	3.03
CV% Acceptance Criteria	10.0	5.0	5.0	15.0	15.0	10.0	10.0	20.0	5.0	5.0	10.0

Sysmex XN-20 Model Level 2											
Measurand (%CV)											
	EO%	BASO%	IG%	NRBC#	NRBC %	RET#	RET%	IRF	RET-He	IPF%	IPF#
Lot 3280	7.33	2.56	2.79	5.68	5.86	5.38	4.10	9.62	1.47	3.88	8.09
Lot 3322	7.41	2.74	2.35	4.82	4.95	7.48	6.09	20.31	7.16	4.65	6.14
Lot 3336	7.50	2.64	2.98	6.10	6.37	5.31	4.81	13.75	4.34	3.34	4.12
CV% Acceptance Criteria	10.0	5.0	5.0	5.0	5.0	10.0	10.0	20.0	5.0	5.0	10.0

Sysmex XN-20 Model Level 3											
Measurand (%CV)											
	EO%	BASO%	IG%	NRBC#	NRBC %	RET#	RET%	IRF	RET-He	IPF%	IPF#
Lot 3280	6.8	2.4	3.1	4.22	3.99	9.39	9.46	11.27	1.81	4.91	6.14
Lot 3322	6.6	2.6	2.8	3.10	3.27	9.01	9.60	15.73	8.18	3.57	4.55
Lot 3336	7.7	2.1	2.8	3.12	3.28	7.88	8.10	13.51	5.91	2.92	3.01
CV% Acceptance Criteria	10.0	5.0	5.0	5.0	5.0	10.0	10.0	15.0	5.0	10.0	10.0

Sysmex XN-21 Model Level 1											
Measurand (%CV)											
	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PLT- F%	RDW	RDW- CV
Lot 3280	2.215	3.07	1.51	4.07	1.92	3.55	4.06	5.6	2.1	1.24	0.89
Lot 3322	1.776	3.74	1.46	4.25	1.68	4.06	4.14	6.1	2.2	1.19	1.06
Lot 3336	2.315	2.77	1.71	4.39	2.16	3.01	4.33	6.4	2.2	1.77	0.77
CV% Acceptance Criteria	5.0	5.0	5.0	5.0	5.0	5.0	5.0	10.0	10.0	5.0	5.0

Sysmex XN-21 Model Level 2											
Measurand (%CV)											
	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PLT-F%	RDW	RDW-CV
Lot 3280	1.80	3.23	0.78	3.93	1.80	3.75	4.16	4.0	5.5	1.66	1.14
Lot 3322	1.23	4.00	0.81	4.39	1.57	4.54	4.65	5.5	3.7	1.36	1.03
Lot 3336	1.67	2.87	1.11	4.28	1.94	3.02	4.27	3.1	4.0	1.52	1.09
CV% Acceptance Criteria	5.0	5.0	5.0	5.0	5.0	5.0	5.0	10.0	10.0	5.0	5.0

Sysmex XN-21 Model Level 3											
Measurand (%CV)											
	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT	PLT-F%	RDW	RDW-CV
Lot 3280	1.29	2.58	0.81	3.13	1.67	2.99	3.21	3.7	2.7	1.42	1.22
Lot 3322	.201	4.28	0.77	4.51	1.50	4.90	4.86	6.5	1.9	1.36	1.07
Lot 3336	0.92	2.55	0.98	3.81	1.73	2.61	3.71	3.3	1.7	1.30	1.69
CV% Acceptance Criteria	5.0	5.0	5.0	5.0	5.0	5.0	5.0	10.0	10.0	5.0	5.0

Sysmex XN-21 Model Level 1											
Measurand (%CV)											
	MPV	NEUT#	LYMPH#	MONO#	EO#	BASO#	IG#	NEUT%	NEUT%	LYMPH %	MONO %
Lot 3280	4.31	3.523	4.63	8.25	7.42	4.49	4.15	2.66	2.66	8.08	4.31
Lot 3322	3.41	5.04	10.77	7.58	3.46	3.73	2.83	4.82	4.82	3.41	5.04
Lot 3336	3.19	5.77	12.14	7.34	4.53	3.79	2.57	5.08	5.08	3.19	5.77
CV% Acceptance Criteria	5.0	5.0	10.0	15.0	10.0	5.0	5.0	5.0	5.0	10.0	15.0

Sysmex XN-21 Model Level 2											
Measurand (%CV)											
	MPV	NEUT#	LYMPH#	MONO#	EO#	BASO#	IG#	NEUT%	NEUT%	LYMPH %	MONO %
Lot 3280	2.18	2.62	4.00	8.88	7.78	3.03	3.19	1.96	1.96	8.35	2.18
Lot 3322	2.63	2.73	4.63	9.133	7.65	2.87	2.79	2.32	2.32	9.37	2.63
Lot 3336	1.95	2.95	4.20	9.85	7.82	3.14	3.58	2.24	2.24	9.52	1.95
CV% Acceptance Criteria	5.0	5.0	10.0	15.0	10.0	5.0	5.0	5.0	5.0	10.0	15.0

Sysmex XN-21 Model Level 3											
Measurand (%CV)											
	MPV	NEUT#	LYMPH#	MONO#	EO#	BASO#	IG#	NEUT%	NEUT%	LYMPH %	MONO %
Lot 3280	2.0	2.48	7.76	12.2	6.8	2.35	3.46	1.91	1.91	12.4	1.99
Lot 3322	2.2	2.43	6.37	11.5	6.5	3.07	3.12	1.92	1.92	11.59	2.23
Lot 3336	2.0	2.18	5.69	11.4	7.6	2.21	2.93	1.89	1.89	11.67	1.96
CV% Acceptance Criteria	5.0	5.0	10.0	15.0	10.0	5.0	5.0	5.0	5.0	10.0	15.0

Sysmex XN-21 Model Level 1											
Measurand (%CV)											
	EO%	BASO%	IG%	NRBC#	NRBC %	RET#	RET%	IRF	RET-He	IPF%	IPF#
Lot 3280	7.22	3.62	3.37	10.4	10.11	9.078	6.917	11.00	1.84	2.94	3.74
Lot 3322	7.41	3.26	3.24	9.20	9.62	8.684	6.70	19.44	8.35	2.83	3.52
Lot 3336	7.02	3.71	3.46	8.38	8.61	6.28	5.49	16.37	5.15	2.19	3.03
CV% Acceptance Criteria	10.0	5.0	5.0	15.0	15.0	10.0	10.0	20.0	10.0	5.0	5.0

Sysmex XN-21 Model Level 2											
Measurand (%CV)											
	EO%	BASO%	IG%	NRBC#	NRBC %	RET#	RET%	IRF	RET-He	IPF%	IPF#
Lot 3280	7.3	2.6	2.8	5.7	5.86	5.38	4.1	9.6	1.47	3.88	8.09
Lot 3322	7.4	2.7	2.4	4.8	4.95	7.48	6.1	20.3	7.16	4.65	6.14
Lot 3336	7.5	2.6	3.0	6.1	6.37	5.32	4.8	13.8	4.34	3.34	4.12
CV% Acceptance Criteria	10.0	5.0	5.0	15.0	15.0	10.0	10.0	20.0	10.0	5.0	5.0

Sysmex XN-21 Model Level 3											
Measurand (%CV)											
	EO%	BASO%	IG%	NRBC#	NRBC %	RET#	RET%	IRF	RET-He	IPF%	IPF#
Lot 3280	6.8	2.4	3.1	4.2	4.0	9.4	9.5	11.3	1.9	4.9	6.1
Lot 3322	6.6	2.6	2.8	3.1	3.3	9.0	9.6	15.8	8.2	3.6	4.6
Lot 3336	7.7	2.1	2.8	3.1	3.3	7.9	8.1	13.5	6.0	2.9	3.0
CV% Acceptance Criteria	10.0	5.0	5.0	15.0	15.0	10.0	10.0	20.0	10.0	5.0	5.0

b. *Linearity/assay reportable range:*

Not applicable

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

Value assignments:

Value assignment was performed on three Sysmex XN-10 and three Sysmex XN-20 analyzers using two vials of each control level tested a minimum of five times per vial. A 10-run reproducibility study was conducted at the beginning and end of each product dating claim for the tri-level control on each lot (n=60 per level). Data collected from three lots (3280, 3822, and 3336) from all three sites were used to calculate the mean, standard deviation (SD), and coefficient of variation (CV) for each parameter analyzed. The database allows computation and comparison of data that are used in the assay value assignment process as defined by controlled documents. The expected range values assigned to the measurands were based on the ± 3.0 SD of the total-run data and established product performance characteristics. Total-run encompasses the values generated over multiple combined data sets compiled for all three lots of control.

Reagent Stability

Acceptance criteria for open and closed-vial stability was based on a compilation of the CV% for each measurand over data collected across four different Sysmex XN-20 and XN-21 analyzers, at 3 sites, throughout the stability study claim, with three separately manufactured lots of XN CHECK™.

Open-vial stability: A 7 day open-vial stability claim was validated at the end of the 84-day product expiration claim. Two vials of each control level from each of the three reference lots were analyzed on XN-20 and XN-21 series analyzers in duplicate over a period of eight days. A minimum of four data points were collected at each testing event performed by one operator internally at Streck. On a daily basis, vials were removed from storage and mixed in accordance with the instructions for use to simulate daily customer usage/handling.

Closed-vial stability: Three separately manufactured lots of XN CHECK™ lots were set up to validate closed-vial stability performance throughout the 84-day stability study at refrigerated temperatures (2-8C). Two vials of control per level from each reference lot were used at each testing interval for this study. Data was collected internally with one operator on one instrument at each testing event. A minimum of four data points were collected at each testing event for 85 days to cover the 84-day closed-vial stability claim. Data were collected and analyzed using CLSI EP5-A2 methods on the XN-20 and XN-21 series analyzers.

All reported CV% values for open and closed-vial reagent stability study were within the acceptable threshold values as shown in the tables for the acceptance criteria above in section M.1 (a).

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.