

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

A. 510(k) Number:

k141962

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Assayed hematology parameters: WBC ($10^3/\mu\text{L}$), RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%),
PLT ($10^3/\mu\text{L}$), and RET (%)

D. Type of Test:

Quantitative

E. Applicant:

Streck Inc.

F. Proprietary and Established Names:

XM-CAL™

G. Regulatory Information:

1. Regulation section:

21 CFR § 864.8150 - Calibrator for cell indices

2. Classification:

Class II

3. Product code:

KRX-Calibrator for cell indices

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include: WBC ($10^3/\mu\text{L}$), RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), PLT ($10^3/\mu\text{L}$), and RET (%).

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 CAL™ 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 single level calibrator is packaged in polypropylene plastic vials with screw caps. The vials will be packaged in (5) wellled or (1) 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):

XN CAL™

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

k120745

3. Comparison with predicate:

Similarities		
Item	Device-	Predicate
Intended Use	XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-20) analyzers. Assayed	Same

Similarities		
Item	Device-	Predicate
	parameters include: WBC ($10^3/\mu\text{L}$), RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), PLT ($10^3/\mu\text{L}$), and RET (%).	
Reagents	XN CAL 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
Storage conditions	2-8°C	Same
Open vial stability	4 hours	Same

Differences		
Item	Device	Predicate
Closed-Vail Stability	49 days	35 days

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

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

L. Test Principle:

XN CAL™ was designed to function as a substitute for fresh whole blood to calibrate the Sysmex XN10/20, and XN 11/21 series hematology analyzers. This product is for *in-vitro* diagnostic use to calibrate the following parameters: RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), PLT ($10^3/\mu\text{L}$), WBC ($10^3/\mu\text{L}$), and RET (%).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Data were collected at two internal sites and at one external site across 3 different Sysmex XN-21 model analyzers with 3 separately manufactured lots of XN-CAL™. Studies were conducted for each lot at all three (3) sites. Each site performed 10 consecutive runs on each XN-21 Series Instrument with separate vials of calibrator from each lot. Calibration materials were shipped, stored, mixed, and handled in accordance with the instructions for use. The acceptance criteria were based on a compilation of the CV% for each parameter reported. Results across the three

separately manufactured lots of XN CAL™ demonstrated consistent recovery across multiple instruments, at multiple sites within the parameter specific assay assignment set forth for each measurand (see tables 1 and 2 below).

Measurand (%CV)						
Table 1						
Lot	WBC	RBC	HGB	HCT	PLT	RET
3287	1.74	0.80	0.8	2.1	2	4.93
3315	1.42	1.94	1.0	3.0	3	5.52
3343	1.62	4.77	0.9	5.7	6	5.07
SD	0.11	0.02	0.12	1.3	8.4	0.10
Mean	7.0	4.3	12.9	35.2	235	2.00
CV% Acceptance Criteria	5.0	5.0	5.0	10.0	10.0	10.0

Sysmex XN-21 model for XN-CAL														
Table 2			Within Run		Between Run		Between Instrument		Between Lot		Between Site		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	180	7.008	0.092	1.31	0.016	0.23	0.092	1.31	0.032	0.46	0.000	0.00	0.134	1.92
RBC	180	4.307	0.035	0.82	0.101	2.35	0.103	2.40	0.089	2.06	0.000	0.00	0.173	4.02
HGB	180	12.93	0.063	0.49	0.035	0.27	0.040	0.31	0.131	1.01	0.131	1.01	0.203	1.57
HCT	180	35.22	0.279	0.79	0.818	2.32	1.096	3.11	0.760	2.16	0.914	2.60	1.834	5.21
PLT	180	235.0	5.474	2.33	7.234	3.08	6.659	2.83	2.698	1.15	0.000	0.00	11.572	4.93
RET	180	2.007	0.061	3.06	0.052	2.57	0.099	4.93	0.059	2.92	0.000	0.00	0.140	6.99

b. *Linearity/assay reportable range:*

Not applicable

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

Value assignment:

Streck performed analyses on three Sysmex XN-21 model analyzers using three lots of calibrator tested 10 times at the beginning and end of the product date claim of 49 days. Assay values were assigned to the parameters assayed (RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), PLT ($10^3/\mu\text{L}$), WBC ($10^3/\mu\text{L}$, RET (%)) generated from the Sysmex XN-21 model based on a statistical analysis of the data collected at Streck and Sysmex US sites. Final assignment values were determined using total precision data collected and established product performance characteristics. Expected range values assigned to each of the measurand were based on 2.5 SD from the total-run data collected for XN CAL™. All lot specific assay values will be included on the lot

specific assay sheet for each manufactured lot of XN-CAL. An assay sheet will be included for each lot number of XN CAL in each product package.

Reagent Stability

The acceptance criteria for open and closed-vial stability were based on a compilation of the CV% for each measurand (RBC ($10^6/\mu\text{L}$), HGB (g/dL), HCT (%), PLT ($10^3/\mu\text{L}$), WBC ($10^3/\mu\text{L}$, RET (%)) over data collected across three different Sysmex XN-21 analyzers, at three sites, throughout the product stability claim period, using 3 lots of XN CAL™.

Open-vial stability: A 4-hour real-time open-vial stability claim was conducted at the end of the 49-day stability study at one internal site on the Sysmex XN-21 model analyzer. Two vials of calibrator from each of the three reference lots# (3287, 3315, 3343) were analyzed four times at two time intervals over two consecutive days (n=8) on one analyzer.

Closed-vial stability: A real-time 49-day closed-vial study was conducted on the Sysmex XN-21 model analyzers. Two vials of calibrators from each of the three reference lots# (3287, 3315, 3343) were analyzed four times at 21 time interval (n=84) over 53 days across all the 3 sites. Data was collected at one time interval beyond the 49-day stability claim. Data were collected and analyzed using CLSI EP5-A2 methods on the XN-21 model 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).

Traceability

XN CAL™ is calibrated to whole blood following the guidelines outlined in the following:

- CLSI H26-A2-Validation, Verification and Quality Assurance for Automated Hematology Analyzers.
- CLSI Document H7-A3, Procedure of Determining Packed Cell Volume by the Microhematocrit Method, October 2000.
- CLSI Document H15-A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood, December, 2000.
- ICSH Expert Panel on Cytometry, The Assignment of Values to Fresh Blood Used for Calibrating Automated Blood Cell Counters 1988 Clinical Lab Haemat 10:203-212.
- ICSH Expert Panel on Cytometry, Platelet Counting by the RBC/Platelet Ratio Method-March, 2001 American Journal of Clinical Pathology

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 product 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.