

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM
ASSAY ONLY**

A. 510(k) Number:

k141955

B. Purpose for Submission:

Additional or Expanded Indications

C. Measurand:

Assayed hematology parameter: PLT-F ($10^3/\mu\text{L}$)

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

XN-Cal™ PF

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 PF is used for the calibration and calibration verification of Sysmex XN Series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include: PLT-F ($10^3/\mu\text{L}$).

2. Indication(s) for use:

XN CAL PF is used for the calibration and calibration verification of Sysmex XN Series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include: PLT-F ($10^3/\mu\text{L}$).

3. Special conditions for use statement(s):

Prescription use only.

4. Special instrument requirements:

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

I. Device Description:

XN CAL™ PF is an in-vitro diagnostic product that contains the following: stabilized red blood cell component(s) and stabilized platelet component(s) in a preservative medium. The product 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™ PF

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

k120747

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Reagents	XN CAL PF contains the following: stabilized red blood cell component(s), and stabilized platelet component(s) in a preservative medium.	Same
Storage Conditions	2-8°C	Same
Open Vial Stability	4 hours	Same

Differences		
Item	Device	Predicate
Intended Use Statement	XN CAL PF is used for the calibration and calibration verification of Sysmex XN Series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include: PLT-F ($10^3/\mu\text{L}$).	XN CAL PF is used for calibration verification of Sysmex (XN-10, XN-20) analyzers. The assayed parameter is: PLT-F ($10^3/\mu\text{L}$).
Closed Vial Stability	49 days	35 days

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

CLSI EP05-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guidelines-Second Edition.

CLSI H26-A2: Validation, Verification, and Quality Assurance of Automated Hematology Analyzers-Second Edition.

L. Test Principle:

XN Cal™ PF was designed to function as a substitute for fresh whole blood to calibrate the Sysmex XN Series (XN-10, XN-11, XN-20, XN-21) instruments. XN CAL™ PF is an in-vitro diagnostic device used by a component human observer to adjust calibration of the PLT-F ($10^3/\mu\text{L}$) measurand on the Sysmex XN Series analyzers (XN-10, XN-11, XN-20, XN-21).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision performance studies were conducted at two sites (Streck and Sysmex America). Each site performed 10 consecutive runs on each analyzer with separate vials of control from three specified lots at the beginning and end of the product dating claim. Control 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 PLT-F. Results collected across the three manufactured lots of XN CAL™ PF demonstrate consistent recovery across the XN-11 and XN-21 instruments at both sites within the parameter specific assay assignment range as demonstrated in the table below.

XN CAL PF CV% Summary

Lot Number	PLT-F (%CV)
3287	1.1
3315	1.9
3343	2.9
CV% Acceptance Criteria	5.0

b. Linearity/assay reportable range:

Not applicable.

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

i. Value Assignment:

Value assignment for XN CAL™ PF was based on data collected across three (3) XN-21 analyzers (one internal Streck and two external Sysmex). Data was collected using three separately manufactured lots (3287, 3315, and 3343) and three primary operators. A 10-run reproducibility study was executed for the calibrator at the beginning and end of the stated product dating (n=60). The acceptance criterion takes into account inter-operator, inter-laboratory, and inter-instrument variability.

ii. Open-Vial Stability:

The 4-hour open-vial stability claim was substantiated by performing duplicate runs over 2-consecutive days at the end of the 49-day end date utilizing: two (2) vials each of three separately manufactured lots (3287, 3315, and 3343), one primary operator, and one XN-21 analyzer at the internal Streck site. Each vial of calibrator was stored in accordance with the instructions for use between 2°-8°C. The calculated CV% values were within the guidelines indicated in the table above M.1 (a).

iii. Closed-Vial Stability:

The 49-day closed-vial stability claim was substantiated by performing duplicate runs over 21 testing dates spanning the 49-day end date claim utilizing: two (2) vials each of three separately manufactured lots (3287, 3315, and 3343), one primary operator, and one XN-21 analyzer at the internal Streck site. Each vial of calibrator was stored in accordance with the instructions for use between 2°-8°C. The study was performed in accordance

with CLSI EP05-A2 to provide long-term within-device expected imprecision estimates. The calculated CV% values were within the guidelines indicated in the table above M.1 (a). The established acceptance criterion takes into account inter-operator, inter-laboratory, and inter-instrument variability.

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 will refer to the lot specific assay sheet included in each manufactured product package.

N. Proposed Labeling:

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

O. Conclusion:

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