

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

A. 510(k) Number:

K070199

B. Purpose for Submission:

New Device

C. Measurand:

Reticulocyte

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

Retic-Chex Linearity for BC

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):

Retic-Chex Linearity for BC is an assayed linearity control kit, which can be used to assess the instrument's accuracy and to verify patient reportable ranges of automated hematology instrumentation capable of enumerating reticulocytes.

2. Indication(s) for use:

Retic-Chex Linearity for BC is an assayed linearity control kit, which can be used to assess the instrument's accuracy and to verify patient reportable ranges of automated hematology instrumentation capable of enumerating reticulocytes.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

I. Device Description:

Retic-Chex Linearity for BC is a suspension of stabilized human red blood cells and simulated human reticulocytes packaged in plastic vials, containing 3.0 mL volumes. The device consists of five levels of reticulocyte percentage range from 0 to 29.5%. Closures are injected molded polypropylene screw top caps. The vials are packaged in a well vacuum formed clam-shell container with the package insert and assay sheet.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Retic-Chex Linearity, Streck, Inc.

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

K000115

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>Retic-Chex Linearity for BC</i>	<i>Retic-Chex Linearity</i>
Intended Use	To assess the instrument's accuracy and to verify patient reportable ranges of automated hematology instrumentation capable of enumerating reticulocytes.	Same
Closed Vial Stability	105 days	105 days
Open Vial Stability	5 days	5 days
Storage Temperature	2 – 10°C	2 – 10°C

Differences		
	Device	Predicate
Formulation	reticulocyte processing	
Ranges: Level 1	0.4 – 1.1%	0.4 – 1.1%
Level 2	4.7 – 6.8%	4.4 – 5.6%
Level 3	9.5 – 12.0%	8.6 – 10.0%
Level 4	14.2 – 17.2%	12.7 – 14.4%
Level 5	26.5 – 29.5%	23.0 – 25.0%

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

H38-P Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard, 1999, NCCLS

L. Test Principle:

Laboratory agencies mandate that laboratories substantiate their test methods throughout the reportable range for patient test results. Circumstances which may call for verification include installation, major preventative maintenance, unusual trends in control performance, or whenever recommended by the instrument manufacturer. Retic-Chex Linearity for BC contains retic concentrations which span typical patient reportable ranges; allowing the user to comply with these guidelines.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility and comparison to whole blood was performed on two lots of Retic-Chex Linearity for BC and two whole blood samples using the Beckman Coulter® Gen•S hematology analyzer. Each value was calculated from 3 consecutive analyses performed on a single vial of product. Reproducibility is expressed as a CV% and comparably to whole human blood with respect to run to run recovery.

b. Linearity/assay reportable range:

Not Applicable.

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

Open vial stability was assessed by the analysis of two lots to verify performance throughout the 5 day open vial dating (one vial per level). Data was collected at least 4 times during the 5 day period. All lots performed as expected, with parameter recovery within the established assay ranges.

Closed vial stability was assessed by performing analysis of one vial per level from each of two lots once at least two times per month throughout the 105 day expiration dating. No significant trends occurred and there was a consistent recovery of values within the indicated assay range.

Parameter value assignments:

Retic-Chex Linearity for BC is designed as a multi-level reticulocyte control as well as a set of true linearity samples. Each level is prepared by making quantitative dilutions of level 5. At least 3 vials of each level are randomly selected and sampled three times. The results are compiled to obtain an assay value and range for each Level. Expected Range assigned to the assay are based on an estimate of the standard deviation for the assay data.

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:

An expected values sheet is provided with tolerance limits established during the value assignment process. However, it is recommended that each laboratory establish its own acceptance criteria.

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.

