

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

A. 510(k) Number:

K060083

B. Purpose for Submission:

New Device

C. Measurand:

Nucleated Red Blood Cells (nRBC)

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

nRBC-Chex for LH

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625, Hematology quality control mixture

2. Classification:

Class II

3. Product code:

GLQ, Mixture, Control, White Blood and Red-Cell Indices

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

nRBC-Chex for LH is an assayed whole blood control designed to evaluate the accuracy and precision of the Beckman Coulter® LH 750 in its measurement of the nucleated red blood cell parameter.

2. Indication(s) for use:

nRBC-Chex for LH is an assayed whole blood control designed to evaluate the accuracy and precision of the Beckman Coulter® LH 750 in its measurement of the nucleated red blood cell parameter.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

nRBC-Chex for LH is to be used on Beckman Coulter® LH 750 instruments.

I. Device Description:

nRBC-Chex for LH is stabilized suspension of human and animal blood, in a solution containing biological salts and anti-microbial preservatives. The product is packaged in plastic vials containing 4ml. The closures are polypropylene screw caps with polyethylene liners. There are two different levels. Level 1 has a low count and Level 2 has a higher count. The vials are packaged in a six (6) or twelve (12) well vacuum formed “clam-shell” container with the package insert/assay sheet. The product must be stored at 2-10 ° C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Para 12® Plus Retics

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

K000945

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>RBC-Chex for LH</i>	<i>Para 12® Plus Retics</i>
Intended Use	For use as a quality control material to evaluate the accuracy and precision of the Beckman Coulter LH 750 in its measurement of the nucleated red blood cell parameter.	For use as a control for evaluating the accuracy and precision of hematology instruments that provide a white cell differential.
Contents	Human and animal cells	Same with the addition of platelet components
Closed vial stability	75 days	Same

Differences		
	Device	Predicate
Evaluation parameters	RBC, WBC, nRBC	Same. Parameters associated with CBC, white cell five-part differential, reticulocyte characterization and platelets.

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

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

L. Test Principle:

Laboratories require assayed material for quality control of automated, semi-automated and manual procedures that measure whole blood parameters. Daily use of this whole blood control provides quality control data for confirming the precision and accurate of instrument operations.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility studies were performed on three lots of each level of nRBC Chex for LH control. Each value was calculated from 10 consecutive analyses performed on a single vial of product. Reproducibility is expressed as a CV%.

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 both room temperature and refrigerated samples of two lots, 3 runs per level at day 1 through day 7 and also at day 14. All lots performed as expected, with parameter within the established assay ranges.

Closed vial stability was assessed by performing analysis of one vial per level from each of three lots once a week throughout the 75 day expiration date. No significant trends occurred and there was a consistent recovery of values within the indicated assay range.

Site to Site Testing was performed at eight alternate sites. Two test lots were provided to determine the consistency of the assay range. The two levels performed within the assay range.

Parameter value assignments:

The nRBC-Chex for LH product is manufactured and assigned based on instrument specific requirements.

A minimum of three vials per level are tested on the analyzer application – Beckman Coulter LH 750. Each vial is tested for a minimum of two test events performed on different dates. A ten-run reproducibility event is performed using a vial from each level on each instrument application in addition to the tests listed above. This data is included in the value assignment database. When possible the product being assigned is run in conjunction with the whole blood calibration event to provide direct traceability to the reference method.

The data is entered into the validated QC link database program which calculates mean, standard deviation, and coefficient of variation for each parameter analyzed. Final assay assignment values are determined using the

data collected, parity comparisons and established product performance characteristics. Expected range values assigned to the assay are based on the standard deviation of 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:

Mean assay values provided for each parameter are derived from replicate analyses on calibrated instruments. The assay values are obtained using reagents recommended by instrument manufacturers and are to be used for instrument control; they are not absolute assays for calibration. It is recommended that each laboratory establish its own mean and limits for each parameter upon receipt of a new lot. The expected ranges listed in the assay insert represent estimates of variation due to different laboratories, instrument calibration, maintenance, and operator technique.

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.