

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

A. 510(k) Number:

K080016

B. Purpose for Submission:

New Device

C. Measurand:

Nucleated Red Blood Cells (n-RBC)

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

nRBC-Chex for ADVIA®

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

GJR

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

nRBC-Chex for ADVIA® is an assayed whole blood control designed to evaluate the accuracy and precision of the Siemens Healthcare Diagnostic Inc. hematology analyzers in the measurement of the nucleated red blood cell parameter.

2. Indication(s) for use:

nRBC-Chex for ADVIA® is an assayed whole blood control designed to evaluate the accuracy and precision of the Siemens Healthcare Diagnostic Inc. hematology analyzers in the measurement of the nucleated red blood cell parameter.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

For use on the Siemens Healthcare Diagnostics Inc. hematology analyzers, ADVIA

I. Device Description:

nRBC-Chex for ADVIA® is a 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 4 ml. 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 will be packaged in two (2) or twelve (12) well vacuum formed “clam-shell” containers with the package insert/assay sheet. The product must be stored at 2 – 10°C.

J. Substantial Equivalence Information:

1. Predicate device name(s):

nRBC-Chex for LH

2. Predicate K number(s):

K060083

3. Comparison with predicate:

Similarities		
<i>Item</i>	<i>nRBC-Chex for DVIA®</i>	<i>nRBC-Chex for LH</i>
Intended use	An assayed whole blood control designed to evaluate the accuracy and precision of the Siemens Healthcare Diagnostic Inc. hematology analyzers in the measurement of the nucleated red blood cell parameter.	An assayed whole blood control designed to evaluate the accuracy and precision of the Beckman Coulter LH 750/LH755 in its measurement of the nucleated red blood cell parameter.
Parameters	RBC, WBC, nRBC	Same
Storage temperature	2 – 10° C	Same

Differences		
<i>Item</i>	<i>nRBC-Chex for DVIA®</i>	<i>nRBC-Chex for LH</i>
Closed vial stability	45 days	75 days

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

H380-P, Calibration and Quality Control of Automated Hematology Analyzers, April 1999, CLSI

L. Test Principle:

Laboratories require assayed material for quality control of automated, semi-automated and manual procedures for whole blood parameters. Daily use of these whole blood controls provides quality control data for confirming the precision and accuracy of instrument operation. Use of stabilized cell preparations for controlling laboratory testing protocols is an established procedure. When handled like a patient sample and assayed on a properly calibrated and functioning instrument, the whole blood control will provide values within the expected range indicated on the assay sheet.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Reproducibility studies were performed on three lots of each level (Level 1 and Level 2) of nRBC-Chex control. Each value was calculated from 10 consecutive analyses performed on a single vial of control.

b. *Linearity/assay reportable range:*

Not applicable.

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

Value assignment: A minimum of three vials per level are tested on the analyzer application – Siemens Healthcare Diagnostic, Inc. ADVIA® 2120. Each vial is tested for a minimum of two test events (in duplicate) are performed on different dates. The data is entered into the validated QC link database program which calculates mean, standard deviation, and coefficient of variation for each parameter. Final assay assignment values are determined using the data collected parity comparison and established product performance characteristics.

Open vial stability: Three lots were set up to verify performance throughout the 14 day open vial dating. Data was collected, at refrigerated temperature (2-10°C), at least three (3) times during the 14 day study from a single vial per level. All lots performed as expected, with parameter recovery within the established assay range.

Closed vial stability: Three lots were set up to verify performance throughout the 45 day expiration date at refrigerated temperature (2-10°C). No significant trends occurred and there was consistent recovery of values within the indicated assay range.

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 user is directed to refer to the product assay sheet accompanying the product insert. The mean assay values provided for each parameter are derived from replicate analyses on calibrated instruments. It is recommended upon receipt of a new lot of control the user should establish its own mean and limits. However, the control means established by the laboratory should fall within the expected range listed for the control.

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.