

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

A. 510(k) Number:

K063218

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:

e-CHECK (XE)

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):

e-CHECK (XE)TM is intended to be used as a control for complete blood cell count (CBC), white blood cell differential, reticulocyte and nucleated red blood cell (NRBC) parameters on Sysmex XE – series instruments.

2. Indication(s) for use:

e-CHECK (XE)TM is intended to be used as a control for complete blood cell count (CBC), white blood cell differential, reticulocyte and nucleated red blood cell (NRBC) parameters on Sysmex XE – series instruments.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

e-CHECK (XE)TM is to be used on Sysmex XE – series instruments.

I. Device Description:

e-CHECK (XE) is a suspension of stabilized human and animal blood packaged in glass vials, containing 4.6 mL volumes. Closures are injected molded polypropylene screw top caps. This device consists of three levels: Low CBC/High Retic (Low Level), Normal CBC/Intermediate Retic (Normal Level), and High CBC/Low Retic (High Level). The vials are packaged in a welled vacuum form clam-shell container with the package insert and assay sheet.

J. Substantial Equivalence Information:

1. Predicate device name(s):

e-CHECK, Streck, Inc.

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

K994388

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>e-CHECK (XE)</i>	<i>e-CHECK</i>
Intended Use	e-CHECK (XE) TM is intended to be used as a control for complete blood cell count (CBC), white blood cell differential, reticulocyte and nucleated red blood cell (NRBC) parameters on Sysmex XE – series instruments.	e-CHECK is intended to be used as a control for complete blood cell count (CBC), white cell 5-part differential, and reticulocyte parameters on Sysmex XE – 2100 hematology instrument.
Contents	Stabilized human red blood cells, human white cells, and simulated platelets with the addition of simulated human nucleated red blood cells (NRBCs).	Stabilized human red blood cells, human white cells, and simulated platelets.
Evaluation parameters	Complete blood cell count (CBC), white blood cell differential, reticulocyte, and nucleated red blood cell (NRBC).	Complete blood cell count (CBC), white blood cell differential and reticulocyte.
Open Vial Stability	7 day	7 day
Storage Temperature	2 – 8°C	2 – 8°C

Differences		
	Device	Predicate
Closed Vial Stability	84 day	73 day

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

H38-P *Calibration and Quality Control of Automated Hematology Analyzers; Proposed Standard, 1999, 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 and comparison to whole blood was performed on three lots of each level of e-CHECK and two whole blood samples using the Sysmex XE – 2100 hematology analyzer. Each value was calculated from 10 consecutive analyses performed on a single vial of product. Reproducibility is expressed as a CV%. All calculations were performed using Microsoft Excel spreadsheet statistical functions.

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 (2-8°C) samples of three lots, at least 3 runs per level a day through a 7 day open vial period. 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 at least one time per month throughout the 84 day expiration dating. No significant trends occurred and there was a consistent recovery of values within the indicated assay range.

Parameter value assignments:

The e-CHECK value assignment is based on instrument specific requirements. Replicate analyses on multiple vials are performed on the analyzer application – Sysmex XE Series analyzers. Assay analysis is performed using two vials, testing each vial a minimum of five times. This ten-run reproducibility event is analyzed to assure that the mean values and CV% meet instrument specific requirements. The data is forwarded to Sysmex for further analysis. 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 and established product performance characteristics.

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:

Assay means provided by the accompanying assay data sheet are not intended for use as analyzer quality control (QC) file target values. It is recommended that laboratories establish their own QC target values for each new lot number.

Assay expected ranges represent variation between analyzers and are not to be used as QC file limits. Each laboratory should establish control limits based on its analyzer's normal CV.

Suggested QC Limits are available from Sysmex for new users to ensure stable performance until a laboratory's own control limits can be set.

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.