

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

A. 510(k) Number:

K083926

B. Purpose for Submission:

New Device

C. Measurand:

CD4 Lymphocyte

D. Type of Test:

Quantitative

E. Applicant:

Streck, Inc.

F. Proprietary and Established Names:

CD4 Count

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625, White Cell Control

2. Classification:

Class II

3. Product code:

GGL

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

CD4 Count is intended to be used as an assayed whole blood quality control for evaluating white blood cells subsets on a flow cytometry instrument.

2. Indication(s) for use:

CD4 Count is intended to be used as an assayed whole blood quality control for evaluating white blood cells subsets on a flow cytometry instrument.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

I. Device Description:

CD4 Count is a suspension of stabilized human red blood cells and white blood cells in a preservative medium packaged in a plastic vial containing 2.5 ml volumes. The vials are packaged in a vacuum formed “clamshell” box. CD4 Count is supplied in two levels (Normal and Low).

J. Substantial Equivalence Information:

1. Predicate device name(s):

CD-Chex® Plus BC

2. Predicate K number(s):

K051633

3. Comparison with predicate:

Similarities		
<i>Item</i>	<i>CD4 Count</i>	<i>CD-Chex® Plus BC</i>
Intended use	Used as an assayed whole blood quality control for evaluating white blood cells subsets on a flow cytometry instrument.	Designed to serve as a quality control specimen for quality clinical flow-cytometric procedures performed with Beckman Coulter flow cytometry instruments.

Similarities		
<i>Item</i>	<i>CD4 Count</i>	<i>CD-Chex® Plus BC</i>
Open vial stability	30 days	Same
Closed vial stability	60 days	90 days
Storage temperature	2 – 10° C	Same

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

Not Applicable.

L. Test Principle:

Daily use of this whole blood control 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:

Run-to-Run reproducibility studies were performed on three lots of each level. Each value was calculated from 10 consecutive analyses performed on a single vial of each. Reproducibility is expressed as a CV%, which is calculated by dividing the standard deviation by the mean value and multiplying by 100. The CV% are within acceptable limits.

b. Linearity/assay reportable range:

Not applicable.

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

Value assignment: Assay values are assigned to each lot by replicate analysis. A minimum of two vials per level are tested on the BD FACSCount. Each vial is tested for a minimum of three test events 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 analyzed. Final assay assignment values are determined using the data collection and established product performance characteristics.

Alternate Site Testing: One test lot was provided to three sites to determine if they could recover results consistent with the values assigned. One vial of each level was run 10 times on the Becton Dickinson FACSCount analyzer. The two levels performed within the assay range.

Open vial stability: Normal and Low Levels from two lots were run twice a week for 30 days to establish open vial stability. On the week days the vials were not run they were brought to room temperature, mixed and opened. Each vial was returned to refrigerated storage (2-10°C) between analysis periods. All lots performed as expected, with parameter recovery within the established assay ranges. The stability study is within acceptable limits.

Closed vial stability: Normal and Low Levels from three lots were run every 7 – 20 days for at least 60 days. The vials were stored in a monitored refrigerator between 2-10°C between analysis periods. No significant trends occurred and there was consistent recovery of values within the indicated assay range. The stability study is within acceptable limits.

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 mean and expected assay values provided for each parameter are derived from replicate analyses on calibrated instruments. The assay values are obtained using reagents recommended by instrument manufactures and are to be used for instrument control (they are not absolute assay for calibration). Upon receipt of a new control lot, it is recommended that an individual laboratory establish its own mean and limits of each parameter. However, the control mean established by the laboratory should fall within the expected range specified for the control. The expected ranges listed 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.