

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

A. 510(k) Number:

K051633

B. Purpose for Submission:

New Device

C. Measurand:

Lymphocytes, CD2, CD3, CD3/CD4, CD5, CD3/CD8, CD19, CD20, CD3/CD16,
CD3/CD56, HLA-DR

D. Type of Test:

Quantitative, Semi-quantitative

E. Applicant:

Streck Laboratories

F. Proprietary and Established Names:

CD-Chex® Plus BC

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625, Hematology quality control mixture

2. Classification:

Class II

3. Product code:

GGL, White Cell Control

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

CD-Chex® Plus BC is designed to serve as a quality control specimen for clinical flow cytometric procedures performed with Beckman Coulter flow cytometry instruments.

2. Indication(s) for use:

CD-Chex® Plus BC is designed to serve as a quality control specimen for clinical flow cytometric procedures performed with Beckman Coulter® flow cytometry instruments.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

CD-Chex® Plus BC is to be used on Beckman Coulter® flow cytometry instruments.

I. Device Description:

CD-Chex® Plus BC is a suspension of stabilized human red blood cells and human white blood cells packaged in a plastic vial containing 3.0ml volumes. The vials are packaged in a vacuum formed “clam-shell” box.

J. Substantial Equivalence Information:

1. Predicate device name(s):

CD-Chex® Plus

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

K960894

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>CD-Chex® Plus BC</i>	<i>CD-Chex® Plus</i>
Intended Use	For use as a quality control material for Beckman Coulter® flow cytometry.	For use as a control when evaluating monoclonal antibody binding by flow cytometry.
Control Contents	Stabilized human blood in a preservative medium.	Same

Differences		
Item	Device	Predicate
Closed vial stability	60 days	90 days

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

No applicable.

L. Test Principle:

CD-Chex® Plus BC control cells possess surface antigens detectable with monoclonal antibodies. When these cells are stained with fluorescent antibodies and analyzed by flow cytometry they provide a reference for normal peripheral blood leukocytes.

Subset of leukocytes can be distinguished on the basis of light scatter properties as well as the presence of cell surface antigens. CD-Chex® Plus BC is designed to represent normal peripheral blood leukocytes where lymphocytes, monocytes, and granulocytes are distinguishable on the basis of light scatter properties.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable.

b. Linearity/assay reportable range:

Not Applicable.

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

Stability analyses were performed with a Beckman Coulter EPICS XL flow cytometer using tetraONE and System II software. Three test lots of CD-Chex Plus® BC control normal and two test lots of CD-Chex® Plus BC abnormal control were used to establish the performance characteristics of the product.

Closed vial stability was assessed by performing analysis on fresh vial sets during the first week after the ship date and at 30 and 60 days thereafter. 2-Color “% Recovery” values for each phenotype were derived from a single analysis on a single sample tube. 4-Color “% Recovery” and Absolute counts for each phenotype were derived by analyses of two sample preparation tubes. The data presented demonstrated that the product provides reliable and stable data for both 2-Color and 4-Color lymphocyte phenotype makers over a time period of 60 days.

Open vial stability was performed on one lot to verify that the product would remain stable and provide useful data under the conditions of day to day use. A single vial was analyzed at 1, 14, 21, and 30 days with 2-Color and 4-Color technologies. Stable data recovery was produced when the product was subjected to daily use.

Alternate Site Testing

One test lot was provided to four laboratories to determine the consistency of the values assigned. “% Recovery” and Absolute count results for all laboratories were consistent with the assigned assay value.

Assay values were assigned to each lot by replicate analysis of samples from two vials of product

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 monoclonal antibody are derived from triplicate analyses on calibrated flow cytometers. It is recommended that at least five consecutive analyses be performed on a properly aligned flow cytometer for each antibody to establish the assay mean.

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.