

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

A. 510(k) Number:

K040107

B. Purpose for Submission:

New device

C. Analyte:

Blood Collection Tube

Type of Test:

Collection and preservation of peripheral blood cells

Applicant:

Streck Laboratories

Proprietary and Established Names:

Cyto-Chex® BCT

D. Regulatory Information:

1. Regulation section:
21 CFR 862.1675
Tubes; vials; systems; serum separators; blood collection
2. Classification:
Class II
3. Product Code:
JKA
4. Panel:
Chemistry 75

Intended Use:

5. Intended use/ Indication for use:
The Cyto-Chex BCT is for the collection and storage of blood specimens for immunophenotyping WBC by flow cytometry. Recovery of lymphocyte subset cell markers of the HIV panel can be accomplished over a 7 day period following collection.
6. Special condition for use statement(s):
For prescription use only
7. Special instrument Requirements:
None

Device Description:

The Cyto-Chex BCT is an evacuated glass blood collection tube that contains 57 μ L of K₃EDTA anticoagulant and cell preservative. The vacuum is designed to draw approximately 5 mL collection of venous blood. The interior of the tube is sterile.

E. Substantial Equivalence Information:

1. Predicate device name(s):
Immunicon Cell Save™ Tube
2. Predicate K number(s):
K030596
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample	Whole blood	Whole blood
Tube type	Glass	Glass
Sterile	Yes	Yes
Evacuated	Yes	Yes
Differences		
Item	Device	Predicate
Function	Blood leukocyte preservation	Blood leukocyte and circulating epithelial cell preservation
Cap color	Red	Mottled lavender and yellow
Contents	K ₃ EDTA and a cell preservative	Na ₂ EDTA and a cell preservative
Amount of blood withdrawn per tube	5.0 mL	10.0 mL

Standard/Guidance Document Referenced (if applicable):

ISO 6710 Single Use Containers for Venous Blood Specimen Collection
 NCCLS Standard H1-A4 Evacuated Tubes and Additives for Blood Specimen Collection, Fourth Addition; Approved Standard

Test Principle:

Cyto-Chex BCT is an evacuated blood collection tube that is designed to be used with standard phlebotomy supplies for venous blood collection. The tube contains 57 μ L of K₃EDTA anticoagulant and cell preservative and a vacuum that is designed to draw approximately 5 mL of blood. The K₃EDTA absorbs calcium ions, which prevents the blood from clotting. Once a blood specimen is drawn, it begins to age and the cell surface antigens on the leukocytes begin to deteriorate making an analysis of the sub-sets of leukocytes difficult. The purpose of the preservative is to preserve these cell surface antigens for subset analysis by immunophenotyping using flow cytometry.

F. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

NA

b. *Linearity/assay reportable range:*

NA

c. *Traceability (controls, calibrators, or method):*

NA.

d. *Detection limit:*

NA

e. *Analytical specificity:*

A statement was added to the package insert that samples which are icteric, lipemic, or hemolyzed need to be noted on the laboratory report as suspect.

f. *Assay cut-off:*

NA

2. Comparison studies:a. *Method comparison with standard Vacutainer® Tube:*

The Cyto-Chex BCT tube was compared to the BD Vacutainer® tube which is a standard in laboratory practice. Both the BD Vacutainer tube and the BCT tube contain tripotassium EDTA. In addition, the BCT tube contains a preservative. For immunophenotyping lymphocyte subsets using the BD Vacutainer tube, the samples must be counted with 6 hours and processed within 48 hours. The Cyto-Chex is seeking additional storage time up to 7 days.

Healthy and HIV+ donors were compared using flow cytometers in different laboratories. Some of the studies were performed using a single-platform while others required a dual-platform analysis method to calculate total cell counts. The following CD markers were used in the analyses: CD3, CD4, CD8, CD19, CD16/56, and CD45 in which cell counts were calculated. Paired blood specimens from the donors were collected by venipuncture into BD EDTA blood collection tubes and in Cyto-Chex BCT Tubes. Flow cytometric data were collected within 6 hours of blood draw with additional analyses at 3 days and 7 days. Analyses of the 6-hour EDTA tubes were used as the reference or control for all of the Cyto-Chex BCT tubes. Some of the data results are shown below as correlation coefficients. The intercept was set at zero in Excel.

Healthy donors:

CD4

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 1.0089X_{\text{EDTA (6hr)}}; R^2 = 0.9894; n = 25$

3 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0079X_{\text{EDTA (6hr)}}$; $R^2 = 0.9865$; $n = 25$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9892X_{\text{EDTA (6hr)}}$; $R^2 = 0.9714$; $n = 25$

CD8

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 0.9712X_{\text{EDTA (6hr)}}$; $R^2 = 0.9793$; $n = 25$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9587X_{\text{EDTA (6hr)}}$; $R^2 = 0.9812$; $n = 25$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9532X_{\text{EDTA (6hr)}}$; $R^2 = 0.9869$; $n = 25$

CD3

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 0.9978X_{\text{EDTA (6hr)}}$; $R^2 = 0.9827$; $n = 25$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9973X_{\text{EDTA (6hr)}}$; $R^2 = 0.9843$; $n = 25$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9965X_{\text{EDTA (6hr)}}$; $R^2 = 0.9812$; $n = 25$

CD19

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 1.0009X_{\text{EDTA (6hr)}}$; $R^2 = 0.9905$; $n = 25$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0229X_{\text{EDTA (6hr)}}$; $R^2 = 0.9794$; $n = 25$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9896X_{\text{EDTA (6hr)}}$; $R^2 = 0.9925$; $n = 25$

CD16/56

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 0.9706X_{\text{EDTA (6hr)}}$; $R^2 = 0.9517$; $n = 25$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0612X_{\text{EDTA (6hr)}}$; $R^2 = 0.9686$; $n = 25$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9772X_{\text{EDTA (6hr)}}$; $R^2 = 0.9609$; $n = 25$

CD45

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 1.0060X_{\text{EDTA (6hr)}}$; $R^2 = 0.9778$; $n = 25$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0171X_{\text{EDTA (6hr)}}$; $R^2 = 0.9773$; $n = 25$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0023X_{\text{EDTA (6hr)}}$; $R^2 = 0.9779$; $n = 25$

HIV donors:

CD4

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 1.0091X_{\text{EDTA (6hr)}}$; $R^2 = 0.9834$; $n = 20$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9962X_{\text{EDTA (6hr)}}$; $R^2 = 0.9808$; $n = 20$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 0.9634X_{\text{EDTA (6hr)}}$; $R^2 = 0.9892$; $n = 20$

CD8

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 0.9872X_{\text{EDTA (6hr)}}$; $R^2 = 0.9509$; $n = 20$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0231X_{\text{EDTA (6hr)}}$; $R^2 = 0.9310$; $n = 20$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0257X_{\text{EDTA (6hr)}}$; $R^2 = 0.9619$; $n = 20$

CD3

6 Hours: $Y_{\text{Cyto-Chex BCT}} = 1.0065X_{\text{EDTA (6hr)}}$; $R^2 = 0.9575$; $n = 20$
 3 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0201X_{\text{EDTA (6hr)}}$; $R^2 = 0.9512$; $n = 20$
 7 Days: $Y_{\text{Cyto-Chex BCT}} = 1.0092X_{\text{EDTA (6hr)}}$; $R^2 = 0.9799$; $n = 20$

These data show acceptable correlation between the laboratory standard, the BD Vacutainer tube at 6 hours and the Cyto-Chex BCT at 6 hours, 3 days and 7 days.

b. Matrix comparison:

NA.

3. Clinical studies:

a. Clinical sensitivity:

NA

b. Clinical specificity:

NA

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

NA.

5. Expected values/Reference range:

NA.

Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.