

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

A. 510(k) Number:

K080552

B. Purpose for Submission:

Change in volume of reagent in tube.

C. Measurand:

Leukocyte subsets

D. Type of Test:

Qualitative and Quantitative, Flow Cytometry

E. Applicant:

Streck Laboratories, Inc.

F. Proprietary and Established Names:

Cyto-Chex® BCT

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1675

2. Classification:

Class II

3. Product code:

GIM

4. Panel:

75 Chemistry

H. Intended Use:

1. Intended use(s):

Cyto-Chex® BCT is intended for the collection and storage of blood specimens for immunophenotyping of WBC by flow-cytometry. Recovery of lymphocyte subset cell markers of the HIV panel can be accomplished over a 14-day period following collection.

2. Indication(s) for use:

Cyto-Chex® BCT is intended for the collection and storage of blood specimens for immunophenotyping of WBC by flow-cytometry. Recovery of lymphocyte subset cell markers of the HIV panel can be accomplished over a 14-day period following collection.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

I. Device Description:

Cyto-Chex® BCT consists of a standard 13 x 75mm glass blood collection tube containing 75.8 µl of sterile K₃EDTA anti-coagulant and WBC preservative. It is manufactured with a vacuum to draw 5 ml of blood by venipuncture.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Cyto-Chex® BCT

2. Predicate K number(s):

K040107

3. Comparison with predicate:

| Similarities | | |
|---------------|---|-------------------------|
| Item | Cyto-Chex® BCT | Cyto-Chex® BCT(K040107) |
| Intended Use | For the collection and storage of blood specimens for immunophenotyping of WBC by flow-cytometry. | Same. |
| Tube type | Glass | Same |
| Tube size | 13 x75mm | Same |
| Contents | K ₃ EDTA and preservative | Same |
| Sample volume | 5 ml | Same |

| Differences | | |
|-----------------------------|----------------|--------------------------|
| Item | Cyto-Chex® BCT | Cyto-Chex® BCT (K040107) |
| Reagent Volume | 75.8 µl | 57 µl |
| Preservation of HIV markers | 14 days | 7 days |

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

NCCLS Standard H1-A4 Evacuated Tubes and Additives for Blood Specimen Collection, Fourth Addition; Approved Standard

L. Test Principle:

Subsets of leukocytes can be distinguished on the basis of cell surface antigens using fluorescent antibodies and flow cytometry. Qualitative and quantitative changes in leukocyte subsets are used to identify and monitor immunodeficiency and hematologic diseases. Cyto-Chex® BCT is designed to preserve peripheral blood samples qualitative and quantitative leukocyte subset characteristics.

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):*

Not applicable.

- d. *Detection limit:*

Not applicable.

- 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:*

Not applicable.

2. Comparison studies:

- a. *Method comparison with predicate device:*

The following two studies were performed using two different flow cytometers:

The first study was to assess lymphocyte subset cell-surface markers obtained from peripheral blood by collecting samples from 16 healthy donors in EDTA and Cyto-Chex BCT tubes. Within 6 hours both tubes were analyzed on a flow cytometer. Samples collected in Cyto-Chex BCT were held at room temperature and also analyzed at 7 days, 11 days and 14 days. The following markers were used for the analysis: CD3, CD4, CD8, CD16/56 and CD19. Included in the collection data are Absolute cell counts values for each lymphocyte subset as well as the % Recovery for each marker. All correlations were referenced to the EDTA tube at 6 hours.

Summary of Regression for healthy donors (Absolute Counts)

| <i>Marker</i> | <i>Time Interval</i> | <i>Slope</i> | <i>R²</i> |
|---------------|----------------------|--------------|----------------------|
| CD3 | 6 hour | 0.96 | 0.9607 |
| | 7 day | 1.04 | 0.9564 |
| | 11 day | 0.96 | 0.9590 |
| | 14 day | 0.97 | 0.9763 |
| CD4 | 6 hour | 0.96 | 0.9795 |
| | 7 day | 1.04 | 0.9478 |
| | 11 day | 1.02 | 0.9600 |
| | 14 day | 0.98 | 0.9727 |

| | | | |
|---------|--------|------|--------|
| CD8 | 6 hour | 0.95 | 0.9464 |
| | 7 day | 1.00 | 0.9603 |
| | 11 day | 0.94 | 0.9583 |
| | 14 day | 0.95 | 0.9811 |
| | | | |
| CD16/56 | 6 hour | 0.98 | 0.9758 |
| | 7 day | 0.84 | 0.8432 |
| | 11 day | 0.89 | 0.9468 |
| | 14 day | 0.83 | 0.8735 |
| | | | |
| CD19 | 6 hour | 0.98 | 0.9774 |
| | 7 day | 0.95 | 0.9485 |
| | 11 day | 0.94 | 0.9633 |
| | 14 day | 0.93 | 0.9557 |

A second clinical study was to assess the stability of lymphocyte subsets in specimen samples by collecting samples from 10 HIV positive donors and 10 normal donors stored in Cyto-Chex BCT tubes. They were analyzed with the flow cytometer using single-platform methods at 6 hour, 7 days, 11 days and 14 days after collection. The following markers were used for the analysis: CD3, CD4, CD8, CD16/56, CD19 and CD45. The number of lymphocytes positive for the indicated marker was recorded for two runs at each time point. The results were averaged for each donor. Regression analysis was used for the relationship between the average measurement from each time point and the control (EDTA 6 hours). The results showed the estimate slopes are close to 1.0 and R² values are all >0.97 indicating a good agreement between the control and the Cyto-Chex BCT tubes.

Summary of Regression for HIV donors (Absolute Count)

| <i>Marker</i> | <i>Time Interval</i> | <i>Slope</i> | <i>95% CI for Slope</i> | <i>R²</i> |
|---------------|----------------------|--------------|-------------------------|----------------------|
| CD3 | 6 hour | 1.03 | 0.99 to 1.06 | 0.9986 |
| | 7 day | 1.04 | 1.01 to 1.07 | 0.9984 |
| | 11 day | 0.99 | 0.93 to 1.04 | 0.9945 |
| | 14 day | 1.06 | 0.99 to 1.12 | 0.9947 |
| | | | | |
| CD4 | 6 hour | 1.00 | 0.98 to 1.03 | 0.9987 |
| | 7 day | 1.04 | 1.01 to 1.07 | 0.9981 |
| | 11 day | 1.01 | 0.94 to 1.08 | 0.9908 |
| | 14 day | 1.03 | 0.98 to 1.08 | 0.9959 |
| | | | | |
| CD8 | 6 hour | 1.03 | 1.00 to 1.06 | 0.9986 |
| | 7 day | 1.02 | 0.99 to 1.06 | 0.9981 |
| | 11 day | 0.96 | 0.91 to 1.01 | 0.9959 |
| | 14 day | 1.04 | 0.97 to 1.11 | 0.9928 |
| | | | | |
| CD16/56 | 6 hour | 1.11 | 1.02 to 1.20 | 0.9894 |
| | 7 day | 1.08 | 0.99 to 1.07 | 0.9987 |
| | 11 day | 1.02 | 0.95 to 1.09 | 0.9914 |
| | 14 day | 0.99 | 0.87 to 1.10 | 0.9781 |
| | | | | |

| | | | | |
|------|--------|------|--------------|--------|
| CD19 | 6 hour | 1.02 | 0.97 to 1.06 | 0.9966 |
| | 7 day | 0.99 | 0.93 to 1.05 | 0.9939 |
| | 11 day | 0.91 | 0.85 to 0.98 | 0.9911 |
| | 14 day | 0.87 | 0.79 to 0.95 | 0.9855 |
| | | | | |
| CD45 | 6 hour | 1.04 | 0.98 to 1.10 | 0.9944 |
| | 7 day | 1.06 | 1.01 to 1.11 | 0.9955 |
| | 11 day | 1.01 | 0.95 to 1.06 | 0.9951 |
| | 14 day | 1.02 | 0.96 to 1.09 | 0.9933 |

Summary of Regression for normal donors (Absolute Count)

| <i>Marker</i> | <i>Time Interval</i> | <i>Slope</i> | <i>95% CI for Slope</i> | <i>R²</i> |
|---------------|----------------------|--------------|-------------------------|----------------------|
| CD3 | 6 hour | 0.97 | 0.94 to 1.01 | 0.9981 |
| | 7 day | 1.02 | 0.98 to 1.06 | 0.9978 |
| | 11 day | 1.03 | 0.99 to 1.07 | 0.9979 |
| | 14 day | 1.01 | 0.96 to 1.05 | 0.9965 |
| | | | | |
| CD4 | 6 hour | 0.97 | 0.94 to 1.00 | 0.9981 |
| | 7 day | 1.02 | 0.99 to 1.06 | 0.9980 |
| | 11 day | 1.03 | 0.99 to 1.07 | 0.9976 |
| | 14 day | 0.99 | 0.96 to 1.03 | 0.9973 |
| | | | | |
| CD8 | 6 hour | 0.98 | 0.94 to 1.02 | 0.9973 |
| | 7 day | 0.99 | 0.94 to 1.05 | 0.9951 |
| | 11 day | 1.01 | 0.97 to 1.05 | 0.9968 |
| | 14 day | 1.00 | 0.95 to 1.06 | 0.9947 |
| | | | | |
| CD16/56 | 6 hour | 0.98 | 0.93 to 1.03 | 0.9950 |
| | 7 day | 0.98 | 0.93 to 1.04 | 0.9945 |
| | 11 day | 0.96 | 0.92 to 1.01 | 0.9960 |
| | 14 day | 0.95 | 0.90 to 0.99 | 0.9962 |
| | | | | |
| CD19 | 6 hour | 1.00 | 0.97 to 1.03 | 0.9985 |
| | 7 day | 1.01 | 0.95 to 1.07 | 0.9944 |
| | 11 day | 1.01 | 0.96 to 1.06 | 0.9952 |
| | 14 day | 0.98 | 0.92 to 1.03 | 0.9949 |
| | | | | |
| CD45 | 6 hour | 0.98 | 0.96 to 1.01 | 0.9987 |
| | 7 day | 1.01 | 0.96 to 1.05 | 0.9964 |
| | 11 day | 1.03 | 0.99 to 1.06 | 0.9981 |
| | 14 day | 1.01 | 0.97 to 1.04 | 0.9987 |

In both HIV positive and healthy donors, markers CD3, CD4 and CD8 are recovered well within the acceptance criteria for absolute cell counts.

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:

Not applicable.

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.