

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

A. 510(k) Number:

K030815

B. Analyte:

Blood separation

C. Type of Test:

Sample preparation for lithium testing

D. Applicant:

Akers Laboratories, Inc.

E. Proprietary and Established Names:

Blood Cell Separator

F. Regulatory Information:

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

G. Intended Use:

1. Indication(s) for use:
The Blood Cell Separator is intended for use as a sample preparation aid to *in vitro* lithium colorimetric diagnostic testing systems where a precise, micro-volume sample of serum or plasma is required to be collected from a whole blood specimen. The liquid produced by device is dependent upon the sample collected; whole blood collected with an anti-coagulant will produce plasma, and whole blood collected without an anti-coagulant will produce serum.
2. Special condition for use statement(s):
NA
3. Special instrument Requirements:
NA

H. Device Description:

The Blood Cell Separator consists of two components packaged in a single separator device: the membrane system and a capillary tube. Twenty five of each are packaged in the carton.

I. Substantial Equivalence Information:

1. Predicate device name(s):
BD Vacutainer™ glass serum tube, no additive; BD Vacutainer™ EDTA tube
2. Predicate K number(s):
Both BD tubes are pre-amendment
3. Comparison with predicate:

Similarities		
Item	Blood Cell Separator	BD Vacutainers
Intended use	Used to collect and separate blood specimen	Used to collect and separate blood specimens
Principle	Separates cells directly; produces a liquid fraction	Separates cells directly; produces a liquid fraction
Differences		
Item	Blood Cell Separator	BD Vacutainers
Separation method	Filtration using lectin coated membrane system	Centrifugation

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

CDRH Guidance: Medical Device Labeling - Suggested Format and Content; Draft Document Issued on April 25, 1997

K. Test Principle:

The Blood Cell Separator is based upon a multiple layer membrane system coated with lectin designed to separate blood cells and serum/plasma. Whole blood applied to the surface of the membrane system results in serum/plasma which wicks laterally through the device. The residual liquid will then migrate laterally and flow into the capillary tube.

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

Two levels of lithium samples, “Low” and “High” containing 0.5 and 1.2 mEq/L Lithium respectively were each assayed in 10 separation runs per day for 5 days (200 tests). Lithium was measured on the Genysys 5 Spectrophotometer using Trace Lithium Reagent and Standard (K003583). The daily standard deviation obtained during the five (5) day precision study for the Blood Cell Separator ranged from 0.01 mEq/L to 0.04 mEq/L for the low value sample and 0.03mEq/L to 0.07 mEq/L for the high value sample compared to daily standard deviations for the BD Vacutainer™ system of 0.03 mEq/L to 0.08 mEq/L and 0.03 mEq/L to 0.08 mEq/L respectively for the low and high value samples. The composite percent coefficient of variation (%CV) for the Blood Cell Separator system based on 50 samples over 5 days was 8.4% for the low value sample and 5.7% for the high value sample compared to 9.5% and 6.1%, respectively for the BD Vacutainer™ system. These results illustrated equivalent precision performance of the blood cell separator system when compared to the BD Vacutainer™ system.

b. *Linearity/assay reportable range:*

NA

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

NA

d. *Detection limit:*

The assay sensitivity was 0.03 mEq/L with BD Vacutainer™ Tube EDTA plasma separation and 0.03 mEq/L using the Akers Blood Cell Separator separation method illustrating equivalent performance. The data showed that the plasma produced by the Blood Cell Separator did not significantly alter values produced by these samples. Lithium was measured on the Genysys 5 Spectrophotometer using Trace Lithium Reagent and Standard (K003583).

e. *Analytical specificity:*

NA

f. *Assay cut-off:*

NA

2. Comparison studies:

a. *Method comparison with predicate device:*

Studies were performed comparing samples separated with the Blood Cell Separator and EDTA whole blood collected in BD Vacutainer™ tubes. Twenty five spiked whole blood samples, ranging from 0.1 to 2.5 mEq/L at 0.1 mEq/L intervals were separated using the Blood Cell Separator and compared to whole blood collected in BD Vacutainer™ tubes with the plasma separated by centrifugation. Lithium was measured on the Genysys 5 Spectrophotometer using Trace Lithium Reagent and Standard (K003583). The comparison yielded an R value of 0.993 and an R² value of 0.9866.

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):*

NA

4. Clinical cut-off:

NA

5. Expected values/Reference range:

NA

M. Conclusion:

Based upon a Third Party Review of the information provided in this 510(k), this device is substantially equivalent to devices regulated by 21 CFR 862.1675, tubes, vials, systems, serum separators, blood collection; 75 JKA; Class II.

