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

A. 510(k) Number:

K073178

B. Purpose for Submission:

New Device

C. Measurand:

Hematocrit (HCT)

D. Type of Test:

Quantitative

E. Applicant:

R&D Systems, Inc.

F. Proprietary and Established Names:

HCT Extended Hematology Control

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625, Hematology Quality Control Mixture

2. Classification:

   Class II

3. Product code:

   JPK, Mixture Hematology Quality Control

4. Panel:

   81 (Hematology)

H. Intended Use:

1. Intended use(s):

   HCT Extended Hematology Control is an assayed whole blood control designed to monitor values obtained from automated, semi-automated and manual methods.

2. Indication(s) for use:

   It is established laboratory procedure to use a stable control to monitor the performance of diagnostic tests. HCT Extended Hematology Control is an assayed whole blood control designed to monitor values obtained from automated, semi-automated and manual methods.

3. Special conditions for use statement(s):

   Not applicable.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

HCT Extended Hematology Control is an in-vitro diagnostic reagent composed of human erythrocytes suspended in a plasma-like fluid with preservatives. It is an assayed whole blood control designed to monitor values obtained from automated, semi-automated and manual methods. It is sampled in the same manner as a patient specimen. It is supplied in two levels as Abnormal I and Abnormal II. Each vial contains 3.0 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   R&D Systems CBC-7 Hematology Control

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

   K843962

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	HCT Extended Hematology Control	*R&D Systems CBC-7 Hematology Control*
Intended use	An assayed whole blood control designed to monitor values obtained from automated, semi-automated and manual methods.	Same
Biological Source	Human Red Cells	Human Red Cell, Porcine
Closed Vial Stability	2-8°C until expiration date	Same

Differences		
	Device	Predicate
	HCT Extended Hematology Control	*R&D Systems CBC-7 Hematology Control*
Base Matrix	Human erythrocytes suspended in plasma like fluid with preservatives.	Human erythrocytes and simulated leukocytes suspended in plasma like fluid with preservatives.
Analytes	Hematocrit only	Hematocrit, WBC, RBC, HGB, MCV, MCH, MCHC
Open Vial Stability	21 days	14 days

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

Not applicable.

L. Test Principle:

It is established laboratory practice to use a stable control to monitor the performance of diagnostic tests. This control is composed of stable material that provides a mean of monitoring the performance of automated, semi-automated and manual hematocrit methods. It is sampled in the same manner as the patient specimen.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. *Precision/Reproducibility:*

   Three lots of control material were tested between 31 and 41 times to yield an average of less than 5% CV.

   b. *Linearity/assay reportable range:*

   Not applicable

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

   Value assignment: The HCT Hematology Value Assignment protocol is based on current R&D assay ranges for the same or similar instrumentation on other R&D products. One HemataSTAT II, one Microhematocrit Centrifuge, and one Sysmex XE-2100 Automated Hematology Analyzer were used for the value assignment. Means and ranges are chosen at extended stability of the parameter and shifts in instrument calibration. Three lots each of Level I and II were tested by the three methods (with multiple vials and replicate testing) over approximately 4 days. The data was analyzed using linear regression. All CV values were acceptable.

   Open vial stability testing was performed using three lots of Level I and Level II controls on one instrument of each method. Each lot was stored at 2-8°C, allowed to warm to room temperature for 15 minutes, analyzed, and returned to 2-8°C. Data was collected for 6-10 days over the 21 day period. All levels were with in the established range.

   Closed vial stability testing was performed on three lots of Level I and Level II (stored at 2-8oC) and tested at real time points on one instrument of each method. All levels were within the established range. Expiration dating reflects the validated time period that assures adequate device performance throughout shelf life of 75 days.

   d. *Detection limit:*

   Not applicable

   e. *Analytical specificity:*

   Not applicable

  f. Assay cut-off:

  Not applicable

 2. <u>Comparison studies:</u>

  a. Method comparison with predicate device:

  Not applicable

  b. Matrix comparison:

  Not applicable

 3. <u>Clinical studies:</u>

  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. <u>Clinical cut-off</u>**:**

  Not applicable

 5. <u>Expected values/Reference range:</u>

  The target mean values are initially specified at a hematocrit 57-63% for Level I and 66-74% for Level 2. Ranges around the mean are set at ± 5% for Level 1 and ± 6% for Level 2. Users are instructed to refer to the assay table in the labeling for specific instrument models ranges. It is recommended for greater sensitivity that each laboratory should establish its own mean and acceptable range.

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.