

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

A. 510(k) Number:

K070334

B. Purpose for Submission:

New Device

C. Measurand:

Hemoglobin S

D. Type of Test:

Qualitative

E. Applicant:

R&D Systems, Inc.

F. Proprietary and Established Names:

R&D Sickle QC Hematology Control

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625, Hematology Quality Control Material

2. Classification:

Class II

3. Product code:

GGM, Control Hemoglobin

4. Panel:

81 (Hematology)

H. Intended Use:

1. Intended use(s):

R&D Sickle QC Hematology Control is intended to be used as a sickle cell control in testing for the presence of Hemoglobin S in solubility tests.

2. Indication(s) for use:

R&D Sickle QC Hematology Control is intended to be used as a sickle cell control in testing for the presence of Hemoglobin S in solubility tests.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

I. Device Description:

R&D Sickle QC Hematology Control is composed of human erythrocytes suspended in a plasma-like fluid with preservatives, supplied as Control 1 (Negative) and Control 2 (Positive). Each vial contains 2.5 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Streck Sickle-Chex

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

K013316

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	<i>R&D Sickle QC Hematology Control</i>	<i>Streck Sickle-Chex</i>
Intended use	Used as a sickle cell control to test for the presence of Hemoglobin S in solubility tests.	Same
Product Description	A positive and negative control composed of human erythrocytes for solubility tests used to detect Hemoglobin S.	A positive and negative whole blood control to test for the presence of Hemoglobin S in solubility tests and hemoglobin electrophoresis.
Reagent composition	Human erythrocytes suspended in plasma like fluid with preservatives.	Stabilized human red blood cells in a preservative medium.
Storage	2-8°C	2-10°C
Closed Vial Stability	6 months	Same
Open Vial Stability	100 days	Same
Parameters	Hemoglobin/Hemoglobin S	Same

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 presence of sickling hemoglobin S in solubility tests. It is sampled in the same manner as the patient specimen.

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):*

Open and closed vial stability testing was performed on three lots of negative and positive controls (2.5 mL volumes). Vials were stored at 2-8°C for closed vial storage and 15-30° for open vial storage. All controls performed as expected.

Open Vial Stability: 100 days

Closed Vial Stability: 6 months

Value assignment: Human packed red cells are received from vendor and tested once if certification is provide and twice by two different technicians if certification is not provided. A commercial sickle cell test kit is used for this Hemoglobin S testing, and units are processed accordingly to achieve the Control 1 (negative) and Control 2 (positive) 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:

Sickle QC Hematology Control is designed to be handled in the same manner as a patient specimen. The positive control will appear as a cloudy turbid suspension as described in the reagent test kit instruction for use. The negative control will appear as a nearly transparent solution as described in the reagent test kit instruction for use.

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.

