

**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 Sickie 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
	<b><i>R&amp;D Sickle QC Hematology Control</i></b>	<b><i>Streck Sickle-Chex</i></b>
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.

