

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

A. 510(k) Number: k034048

B. Analyte: Glucose

C. Type of Test: Quality Control Material

D. Applicant: R & D Systems, Inc.

E. Proprietary and Established Names: R& D Systems, Inc. GLU-LINE Linearity Control

F. Regulatory Information:

1. Regulation section: 21 CFR §862.1660
2. Classification: Class I
3. Product Code: JJX
4. Panel: 75

G. Intended Use:

1. Intended use(s):

The R & D GLU-LINE Hematology Control is a multilevel control that provides a means of measuring the linearity of glucose analyzers for glucose determinations

2. Indication(s) for use:

The R & D GLU-LINE Hematology Control is a multilevel control that provides a means of measuring the linearity of glucose analyzers for glucose determinations.

3. Special condition for use statement(s): Prescription use

4. Special instrument Requirements: Glucose instruments

H. Device Description:

The GLU-LINE is an in vitro diagnostic reagent composed of human erythrocytes and glucose suspended in a plasma-like fluid with preservatives. This control is a

multilevel control that provides a means of measuring the linearity of glucose analyzers for the glucose parameter.

I. Substantial Equivalence Information:

1. Predicate device name(s):

R & D Systems, Inc. Glucose Hemoglobin Hematology Control

2. Predicate K number(s): K993321

3. Comparison with Predicate:

The R&D GLU-LINE Hematology Control is equivalent to the R&D Glu/Hgb Hematology Control cleared via (K993321). The table below lists the similarities and differences between the Predicate and Proposed device.

Characteristic	Proposed Device: R&D GLU-LINE Hematology Control K034048	Predicate Device R&D Glu/Hgb Hematology Control K993321
Intended Use	GLU-LINE is a multilevel control that provides a means of measuring the linearity of glucose analyzers for glucose parameter determinations.	Similar
Summary	CAP requirements and CLIA regulations both mandate that laboratories establish reportable range for each test method. It is good laboratory practice to verify reportable ranges at initial set up of analyzer, unusual trend or shift in controls and as recommended by the instrument manufacturer.	Similar
Reagents	GLU-LINE is an in vitro diagnostic reagent composed of human erythrocytes and glucose suspended in a plasma-like fluid with preservatives.	Similar
Storage	Store at 2 - 8° C when not in use. Protect vials from overheating and freezing.	Similar
Closed Vial Stability	Unopened vials are stable through the expiration date.	Similar
Open Vial Stability	Sampled product should be used immediately, and then discarded.	Similar

Product Description	The GLU-LINE is an in vitro diagnostic reagent composed of human erythrocytes and glucose suspended in a plasma-like fluid with preservatives. This control is a multilevel control that provides a means of measuring the linearity of glucose analyzers for the glucose parameter.	Is used to monitor the results of analyzers that measure glucose and hemoglobin in whole blood.
Precautions	GLUC-LINE is intended for in vitro diagnostic use only by trained personnel.	Similar
Indications of Deterioration	After mixing, the product should be similar in appearance to fresh whole blood. In unmixed tubes, the supernatant may appear cloudy and reddish; This is normal and does not indicate deterioration. Other discoloration, very dark red supernatant or unacceptable results may indicate deterioration.	Similar
Limitations	The performance of this product is assured only if it is properly stored and used as described in the package insert. Incomplete mixing of the vial prior to use invalidates both the sample withdrawn and any remaining material in the vial.	Similar
Parameters	Glucose	Hemoglobin and Glucose

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

FDA guidance “Points to Consider Guidance Document on Assayed and Unassayed Quality Control Materials”.

K. Test Principle: NA**L. Performance Characteristics (if/when applicable):**1. Analytical performance:

a. *Precision/Reproducibility:* NA

b. *Linearity/assay reportable range:* NA

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

The mean values were derived from replicate analysis. The tests listed in the labeling were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents.

d. Detection limit: NA

e. Analytical specificity: NA

f. Assay cut-off: NA

2. Comparison studies:

a. Method comparison with predicate device: NA

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:

GLU-LINE is prepared by precise dilutions of concentrates stock. The obtained mean will be evaluated against the expected value. The difference between the obtained values and the expected values is compared to acceptable limits. Each lab must define its own acceptable limits that can be used by the laboratory director to establish acceptable analytical performance criteria and a reportable range to ensure test results are consistent with the medical needs of the patient.

M. Conclusion:

Based on the review of the information provided in this submission, I recommend that this device is substantially equivalent to the predicate device R&D Glu/Hgb Hematology Control (K993321), regulated by § 21 CFR 862.1660, Single (Specified) Analyte Controls (assayed and unassayed); 75 JJX; Class I