

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

A. 510(k) Number:

k050961

B. Purpose for Submission:

New Device

C. Analyte:

Glycosylated Hemoglobin

D. Type of Test:

Control Material

E. Applicant:

Bionostics, Inc.

F. Proprietary and Established Names:

RNA1a Control for NycoCard HcA1c

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1660 Quality control material (assayed and unassayed).
2. Classification:
Class I, reserved
3. Product Code:
JJX
4. Panel:
75, Chemistry

H. Intended Use:

1. Intended use(s):
See Indications for Use below.
2. Indication(s) for use:
RNA1a Control for NycoCard HcA1c is intended to be used to monitor and evaluate the analytical performance of the Axis-Shield NycoCard HbA1c reader for the measurement of glycosylated hemoglobin. The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practice. The two levels of controls allow performance within the clinically important range. For In Vitro Diagnostic Use.
3. Special condition for use statement(s):
For Prescription Use Only.
4. Special instrument Requirements:
Axis-Shield NycoCard HbA1c test system.

I. Device Description:

RNA1c Control is for the NycoCard HbA1c reader. The bi-level (abnormal and normal) glycated bovine hemoglobin liquid control contains no human biological material and does not require reconstitution. The control is supplied in two 1.5 mL vials and contains beads, buffers, viscosity adjusters and stabilizers.

The bovine blood sourced from US disease-free cattle and this product can be provided with certificate of health from the USDA Veterinary Services.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Primus Liquid Control for GHb/A1c
2. Predicate K number(s):
k992921
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Intended to be used to monitor and evaluate the analytical performance of the Axis-Shield NycoCard HbA1c reader for the measurement of glycosylated hemoglobin.	For the control of quantitative glycated hemoglobin assays.
Number of Levels	2	2
Analytes	Glycated hemoglobin (HbA1c)	Glycated hemoglobin (HbA1c)
Open Vial Stability	30 days at 2-8 °C	30 days at 2-8 °C
Storage	2-8 °C	2-8 °C
Differences		
Item	Device	Predicate
Closed Stability	12 months at 2-8 °C	9 months at 2-8 °C
Matrix	Glycated bovine hemoglobin in solution with dyed polystyrene beads to simulate total hemoglobin.	Lyophilised, prepared non-diabetic hemolysate. Abnormal level prepared by controlled glycation.

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

Points to consider guidance document on assayed and unassayed quality control material. US FDA, Feb 2 1999

Use of symbols on labels and in labeling of in vitro diagnostic devices intended for professional use, US FDA, Nov 30, 2004.

ISO 13485:2003. Quality Systems: Medical Devices- particular requirements for the application of ISO 9001

ISO 14971:2000. Medical Devices: Application of risk analysis to medical devices.

ISO 15223:2002. Medical Devices- Symbols to be used with medical devices labels, labeling and information to be supplied.

L. Test Principle:

Not Applicable

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

N/A

b. *Linearity/assay reportable range:*

N/A

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

Assigned ranges for the controls are based on replicate assays of representative samples of the product on multiple instruments and lots. Value assigned by this method were evaluated against replicate assays of representative samples (10 tests for each control type) of the product by participating laboratories using the Axis-Shield NycoCard HbA1c reader. The acceptance criterion is a reading of greater than 95% of values reported within assay limits for both the product and the predicate device.

Stability

Closed vial stability was conducted and evaluated at -20 and 5 °C. Evaluation to determine the change from the value at time zero to show less than 10% change in HbA1c recovery over 12 months when stored at -20 or 2-8 °C. The result for normal was 6% and for abnormal was -5%.

Open vial stability was evaluated by testing percent change of HbA1c in vials stored at 2-8 °C daily for 30 days. The percent change in HbA1c over 30 days was -1.4% and +1.8% for normal and abnormal lots respectively.

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

2. Comparison studies:a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:a. *Clinical sensitivity:*

N/A

b. *Clinical specificity:*

N/A

c. *Other clinical supportive data (when a and b are not applicable):*

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:
N/A

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.