

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

A. 510(k) Number:

k050100

B. Purpose for Submission:

The company is introducing of a new product – a control – for an existing 3rd party device.

C. Measurand:

This product under submission serves as a control for a device that simultaneously measures the concentration of hemoglobin via adsorption and the glycosylation state via an immunoassay.

The proposed control uses a glycosylated peptide fragment to mimic the binding target of the immunoassay. The concentration of hemoglobin is mimicked by a red dye.

D. Type of Test:

The product is used as a mimic of human blood of known composition to be used as an assayed quality control material for the HbA1c assay on the Bayer DCA 2000 and DCA 2000+ Analyzers.

E. Applicant:

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

F. Proprietary and Established Names:

RNA1c Hemoglobin A1c Control for Bayer DCA 2000 and DCA 2000+ Analyzers

G. Regulatory Information:

1. Regulation section:

21CFR862.1660 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):

RNA Medical Brand RNA_{1c} Control is an assayed quality control material used for monitoring the performance of Bayer DCA 2000 and DCA 2000+ Analyzers that measure HbA_{1c}.

2. Indication(s) for use:

RNA1c Control for Bayer DCA2000 and DCA2000+ Analyzers is intended to be used to monitor and evaluate the analytical performance of the Bayer DCA 2000 and DCA 2000+ Analyzers that measure HbA_{1c}. 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 monitoring within the clinically important range.

3. Special conditions for use statement(s):

Not applicable

4. Special instrument requirements:

This control is only intended for use with the Bayer DCA 2000 and DCA 2000+ Analyzers.

I. Device Description:

RNA1c Control for Bayer DCA2000 and DCA2000+ Analyzers is an assayed, two level, aqueous liquid control solution consisting of a synthetic peptide identical to the HbA_{1c} epitope in a non-biological aqueous solution with dye to provide the appropriate total hemoglobin value. The concentration of dye and peptide are optimized for use on the Bayer DCA 2000 and DCA 2000+ Analyzers to provide

measurement values for HbA1c equivalent to the predicate device, Bayer DCA 2000 Hemoglobin A1c Normal and Abnormal Control Kit. RNA1c Control for Bayer DCA2000 and DCA2000+ Analyzers is a non-hazardous aqueous solution containing no hemoglobin or other materials of biological origin.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer DCA 2000+ HbA1c Control

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

k021484

3. Comparison with predicate:

Similarities		
Characteristic	Device	Predicate(K021484)
Intended Use	As a quality control solution for use to verify the performance of the Bayer DCA 2000 and 2000+ Analyzers	As a quality control solution for use to verify the performance of the Bayer DCA 2000 and 2000+ Analyzers
Number of Levels	2	2
Appearance	Red	Red (after reconstitution)

Differences		
Characteristic	Device	Predicate(K021484)
Physical State	Liquid	Dry powder
Contents	Synthetic glycosylated peptide and red dye	human hemoglobin A
Storage Characteristics	12 months at 2° - 8°C	13 weeks at 2° - 8°C (after reconstitution)

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

None were referenced in this submission.

L. Test Principle:

The product under submission is used to verify the performance of Bayer Analyzers. The control is treated as a typical sample. Processing is done per instrument instructions.

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):

No Traceability was provided.

The predicate and pre-market devices serve as controls for specific Bayer clinical equipment. The stability of the components is one of the primary criteria for acceptance.

Stability is measured by:

- Open vial aging which mimics handling by the users of the product. These studies involve verifying concentration of the analyte mimics as seen by the Bayer device when the product is stored capped but unsealed at 2 °C to 8 °C.
- Accelerated stability testing which involves storing tested samples at elevated temperatures (25 °C) in an effort to predict their long-term performance.

The reported stability is within the error limits stated with the product. The measured stability is consistent with the shelf life claimed on the product insert.

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:

The performance of this control was verified by comparing it to the existing control on the required Bayer instrument.

The assigned ranges for these controls are based upon replicate assays of samples of the product on multiple instruments and lots of measurement cassettes in accordance with directions accompanying the Bayer analyzers.

Values assigned by this method were evaluated against replicate assays of representative samples of the product by participating laboratories using the DCA 2000 and DCA 2000+ models to confirm >95% of values reported within assay limits for both the product and the predicate device. All values were assigned with instruments and instrument manufacturer's reagents available at the time of the comparison.

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:

Expected values are presented in the labeling for a representative lot for HgbA1c assay on the Bayer DCA 2000 and 2000 + Analyzers as follows:

Control material	Mean	Range
Normal HgbA1c	5.5 %	4.4 – 6.6 %
Abnormal HgbA1c	11.0 %	8.8 – 13.2 %

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.