

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

**A. 510(k) Number:**

k112356

**B. Purpose for Submission:**

New device

**C. Measurand:**

Quality control materials for blood glucose monitoring system

**D. Type of Test:**

Not applicable

**E. Applicant:**

Bionostics, Inc.

**F. Proprietary and Established Names:**

Glucose Meter-Check Control Solution for AgaMatrix

**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:

Clinical Chemistry (75)

## **H. Intended Use:**

1. Intended use(s):

See indication(s) for use below.

2. Indication(s) for use:

The Glucose Meter-Check Control Solution for AgaMatrix is intended for use to verify the performance and correct operation of the AgaMatrix blood glucose monitoring test systems utilizing the WaveSense family of blood glucose test strips. Glucose Meter-Check Control Solution for AgaMatrix is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use.

3. Special conditions for use statement(s):

Prescription Use and Over-the-Counter Use

4. Special instrument requirements:

For use with the following AgaMatrix blood glucose monitoring test systems utilizing the WaveSense family of blood glucose test strips:

- WaveSense™ KeyNote® BGMS (k073573)
- WaveSense™ KeyNote® Pro BGMS (k052762)
- WaveSense™ Presto® BGMS (k073573)
- WaveSense™ Jazz® BGMS (k071393)

## **I. Device Description:**

Glucose Meter-Check Control Solution for AgaMatrix is a buffered aqueous solution with glucose containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation. It consists of viscosity-adjusted, aqueous glucose solution prepared with a single concentration of D-glucose. This solution is intended for use with the blood glucose test systems manufactured by AgaMatrix and utilizing the WaveSense family of blood glucose test strips. The solution contains no hazardous, human or animal derived components.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

AgaMatrix Liberty Control Solution

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

k052762

3. Comparison with predicate:

Item	Device	Predicate
Brand name	Glucose Meter-Check Control Solution for AgaMatrix	AgaMatrix Liberty Control Solution (k052762)
Indications for use	Verify the performance and correct operation of the blood glucose monitoring test systems	Same
Number of levels	One, typical fasting glucose of a non-diabetic subject	Two: normal level, typical fasting glucose of a non-diabetic subject; and high level, elevated blood glucose
Analytes	Glucose	Same
Target ranges (mg/dL)	105 - 158 (Normal)	111 – 169 (Normal) 298 – 448 (High)
Container	6 mL LDPE vial with dispensing tip and cap	Same
Fill volume	4 mL	Same
Color	Blue	Same
Matrix	Buffered, aqueous solution of D-glucose, viscosity modifier, preservatives and other, non-reactive ingredients	Same

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

ISO 15197:2003 In-vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus

ISO 14971:2009 Medical Devices - Application of risk management to medical devices

ISO13485:2003 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

ISO 15223-1:2007 Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

ISO 18113-2:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) – Part 2: In vitro diagnostic reagents for professional use

ISO 18113-4:2009 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) – Part 4: In vitro diagnostic reagents for self testing

EN13640:2002 Stability Testing of In Vitro Diagnostic Reagents

**L. Test Principle:**

Not applicable

**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):*

Traceability and Value Assignment

The Glucose Meter-Check Control Solution is traceable to high precision gravimetry with reagent grade raw materials and calibrated instrumentation. The analytical values for subsequent production lots of material are confirmed by comparison of new production lots of material to the Reference Lots in parallel measurement on the YSI 2300.

Value assignment for test strips is determined for each lot of control solution using three lots of each type of test strips and two meters of each type (of the four claimed AgaMatrix BGMS in the labeling). Ten measurements were performed for each meter/test strip lot of each type of the AgaMatrix BGMS. The assigned values represent a range of -20% to +20% of the mean value of all measurement on all meters and test strips determined by this testing, and are represented on each vial of control solution. The assigned range value is acceptable if > 95% of all individual measurements is within the range.

Stability:

Close bottle stability of 24 months when stored at 2 to 30 °C is claimed in the labeling. The real time stability study protocol was followed to test control solutions from close bottles every three months over a period of 24 to 27 months. The change in glucose concentration in product stored at 30°C as measured by YSI 2300 was compared against reference material stored at 2 to 8 °C. The pre-set acceptance criteria were met.

Open bottle stability of 3 months when stored at 2 to 30 °C is claimed in the labeling. The real time stability study protocol was followed to test control solutions from open bottles every other week over a period of 13 weeks. The change in glucose concentration in product stored at 30°C as measured by YSI 2300 was compared against unopened reference material stored at 2 to 8 °C.

The pre-set acceptance criteria were met.

The product stability during transport was tested for 5 days at -1°F (-20 °C), and 113 °F (45 °C). The change in glucose concentration in product stored at -1°F (-20 °C) and 113 °F (45 °C) as measured by YSI 2300 was compared against reference material stored at 2 to 8 °C. The pre-set acceptance criteria were met. Glucose Meter-Check Control solution for AgaMatrix meets transport stability requirements and can be shipped without special consideration.

*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:

An expected range for the Glucose Meter-Check Control Solution is printed on the vial label of the control solution. The sponsor provides the following in the package insert: “The acceptable range printed on the control solution vial are different from the ranges printed on the test strip vial. When using this Glucose Meter-Check Control Solution, you should always compare your result to the range printed on the control solution vial. (DO NOT compare your results to the acceptable range for any other test strip type.)”

**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.