

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

A. 510(k) Number:

k090943

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for blood glucose monitoring system

D. Type of Test:

Quantitative

E. Applicant:

American Biological Technologies, Inc.

F. Proprietary and Established Names:

AbT Glucose Control Solution

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, single (specified) analyte controls (assayed and unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See indication for use below.
2. Indication(s) for use:
For *in vitro* diagnostic use (i.e. for external use only) by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the Agamatrix WaveSense Presto Blood Glucose Monitor.
3. Special conditions for use statement(s):
For *in vitro* diagnostic use, over-the-counter use.
4. Special instrument requirements:
For use with the AgaMatrix WaveSense Presto Blood Glucose Monitor.

I. Device Description:

The AbT Glucose Control Solution is a viscosity-adjusted, buffered aqueous control solution containing a known quantity of glucose. The product is packaged in a plastic dropper tipped bottle for easy application of the control solution to the test strips and contains red coloration to aid the user to visually confirm application. The product is nonhazardous and contains no human or animal derived materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

WaveSense Normal Control Solution, AgaMatrix, Inc.
Liberty Normal Control Solution, Liberty Healthcare Group, Inc.

2. Predicate K number(s):

k052762 and k063855 respectively.

3. Comparison with predicate:

Item	Device	WaveSense Normal Control Solution	Liberty Normal control Solution
Similarities/Differences			
Intended Use	Used to check the performance of AgaMatrix WaveSense Presto Glucose Monitoring System	Used with the WaveSense-enabled Blood Glucose Meter and WaveSense Test Strips to ensure that the meter and test strips are working together properly	Used to check the performance of Liberty Blood Glucose Monitoring System.
Levels	1	same	same
Analyte	Glucose	same	same
Target	95 – 145 mg/dL	108 – 159 mg/dL ⁽¹⁾	94 – 147 mg/dL ⁽²⁾
Matrix	Buffered aqueous solution of D-Glucose, viscosity modifiers, preservatives, and other non-reactive ingredients	same	same
Container	Plastic bottle with dropper-tip	same	same
Fill Volume	3.6 mL	6 mL	3.6 mL
Color	Red	Blue	Red
Target Population	Professional and home use	same	same

⁽¹⁾ Estimated from WaveSense Presto test strip lots published ranges.

⁽²⁾ Estimated from Liberty Normal Control Solution published control ranges.

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

Evaluation of the Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition (CLSI EP5-A2).

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):*

The D-Glucose used in this control is traceable to an in-house glucose preparation which is traceable to the NIST standard 917b. Values are assigned by repeat analysis using three different lots of AgaMatrix WaveSense Presto test strips and one AgaMatrix WaveSense Presto Blood Glucose Monitor. The mean and standard deviation are used to establish the acceptable range for the AgaMatrix WaveSense Presto Blood Glucose Monitor.

Stability characteristics of the AbT Glucose Control Solution were determined using accelerated and real-time studies. The unopened shelf-life is 24 months and the open vial stability is 90 days at the recommended storage of 36 °F to 86 °F.

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 acceptable range for the AbT glucose control used with the AgaMatrix WaveSense Presto blood glucose monitoring system is printed on the control vial label. When using this control material, users are to compare their control result to the range on the control vial (rather than the range printed on the test strip vial).

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