

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

A. 510(k) Number:

k083549

B. Purpose for Submission:

New Device

C. Measurand:

Glucose

D. Type of Test:

Control material for FreeStyle and FreeStyle Lite Blood Glucose Monitors

E. Applicant:

American Biological Technologies

F. Proprietary and Established Names:

AbT Glucose Control Solution

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR§ 862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The AbT Glucose Control Solution is 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 FreeStyle and FreeStyle Lite Blood Glucose Monitors.

3. Special conditions for use statement(s):

For over the counter use; For *in vitro* diagnostic use

4. Special instrument requirements:

FreeStyle and FreeStyle Lite Blood Glucose Monitors

I. Device Description:

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

J. Substantial Equivalence Information:

1. Predicate device name(s):
Device 1 - Abbott Diabetes Care, Inc. Freestyle Control Solution
Device 2 - Liberty Healthcare Group Liberty Glucose Control
2. Predicate 510(k) number(s):
Device 1 - k031260 (Abbott)
Device 2 - k060481 (Liberty)
3. Comparison with predicate:

Similarities			
Characteristic/ Aspect	Predicate Device No. 1 (FreeStyle Control Solution)	Predicate Device No. 2 (Liberty Glucose Control)	New Product (AbT Glucose Control Solution)
Number of Levels	1	1	1
Analyte	Glucose	Glucose	Glucose
Target on a commercially available analyzer	88 mg/dL	88 mg/dL	88 mg/dL
Target Range on the glucose monitors	80 – 130 mg/dL	80 – 130 mg/dL	80 – 130 mg/dL
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip
Color	Red	Red	Red
Matrix	Buffered aqueous solution of D- Glucose, viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients

Indications for Use	For use with the FreeStyle blood glucose monitoring system in order to ensure that the FreeStyle meter and FreeStyle test strips are working properly.	Used to check the performance of FreeStyle Blood Glucose Systems.	Used to check the performance of FreeStyle and FreeStyle Lite Blood Glucose Systems.
Target Population	Professional and home use	Professional and home use	Professional and home use

Differences			
Fill Volume	4.0 mL	3.6 mL	3.6 mL

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

None were referenced.

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:

The control is traceable to an 88 mg/dL standard of NIST Standard Reference Material 917b as analyzed using a commercially available chemistry analyzer. The 88 mg/dL standard was manufactured in accordance with the NIST “Instructions for Use as a Standard in Clinical Applications” which accompanies the certificate of analysis for SRM917b.

Stability:

Stability testing protocols were reviewed and found to be acceptable. The product has a closed-vial stability developed through real-time testing of 24 months at 2 – 30 °C. Open-vial stability is 90 days after opening at 2 – 30 °C, but should not exceed the printed expiration date.

Value Assignment:

The control lot is tested using a commercially available clinical chemistry analyzer with an expected value of 88 mg/dL. Value assignment protocols for the FreeStyle and FreeStyle Lite blood glucose monitors involve repeat testing to obtain the mean value. The assigned range is based upon a percentage of the obtained mean. The expected results may vary slightly with each lot. The expected range is listed in the product insert for both the FreeStyle and FreeStyle Lite blood glucose monitors. In addition, the product insert for this device alerts the user to use the range indicated in this control's product insert rather than the range provided in the glucose test strip product's insert that applies to another commercially available control material.

- 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:
Not Applicable

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.