

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

A. 510(k) Number:

k090854

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for blood glucose monitoring systems

D. Type of Test:

Quantitative

E. Applicant:

American Biological Technologies, Inc.

F. Proprietary and Established Names:

AbT Glucose Control Solution

G. Regulatory Information:

| Product Code | Classification | Regulation Section | Panel |
|--|-------------------|--------------------|---------------|
| JJX – Quality control material (assayed and unassayed) | Class I, reserved | 21 CFR 862.1660 | 75, Chemistry |

H. Intended Use:

1. Intended use(s):

See indications 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 Contour TS Blood Glucose Monitor.

3. Special conditions for use statement(s):

Over-the-Counter Use

4. Special instrument requirements:

Bayer Contour TS Blood Glucose Monitor

I. Device Description:

The AbT Glucose Control Solution consists of a viscosity-adjusted, aqueous liquid control solution containing a known quantity of 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):

Contour Control Solution, Bayer Healthcare
FDTX Glucose Control Solution, American Biological Technologies, Inc.

2. Predicate K number(s):

k023657 and k081915, respectively

3. Comparison with predicate:

| Similarities/Differences | | | |
|--------------------------|--|--|--|
| Item | Device | Contour TS Control Solution | FDTX Control Solution |
| Indication for Use | To check the performance of the Contour TS Blood Glucose System | For self testing by people with diabetes and by healthcare professional as a quality control check | To check the performance of the Ascensia Contour Blood Glucose System |
| Number of Levels | 1 | 1 | 1 |
| Analyte | Glucose | Glucose | Glucose |
| Target Range | 100-145 mg/dL | 99-142 mg/dL | 100-145 mg/dL |
| Container | Plastic bottle with dropper-tip | Plastic bottle with dropper-tip | Plastic bottle with dropper-tip |
| Fill Volume | 3.6 mL | 2.5 mL | 3.6 mL |
| Color | Red | Red | Red |
| Matrix | Buffer aqueous solution of D-Glucose, a viscosity modifier, preservatives and other non reactive ingredients | Aqueous solution which contains a measured amount of glucose | Buffer aqueous solution of D-Glucose, a viscosity modifier, preservatives and other non reactive ingredients |

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

CLSI EP5-A, Evaluation of the Precision Performance of Clinical Chemistry Devices

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 test strips. The mean and standard deviation are used to establish the acceptable range for the glucose monitoring system.

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 Contour TS blood glucose monitoring system is 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.