

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

A. 510(k) Number:

k091460

B. Purpose for Submission:

New device

C. Measurand:

Control materials for glucose test systems

D. Type of Test:

Quantitative

E. Applicant:

American Biological Technologies, Inc.

F. Proprietary and Established Names:

AbT Glucose Control Solutions Levels 1, 2, 3

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

H. Intended Use:

1. Intended use(s):

Refer to 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 TRUEresult™ and TRUE2go™ Meters and TRUEtest™ Test Strips.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use (for external use only). For over the counter use.

4. Special instrument requirements:

TRUEresult and TRUE2go blood glucose test systems

I. Device Description:

The AbT Glucose Control Solutions consist of buffered aqueous solutions of D-Glucose, a viscosity modifier, preservatives, red dye, and other non-reactive ingredients. The devices are non-sterile, non-hazardous, and contain no human or animal derived materials. The product is packaged in plastic dropper tipped bottles for easy application to the test strip and contains a red coloration to aid the user to visually confirm application of the control.

J. Substantial Equivalence Information:

1. Predicate device name(s):

TRUEtest Glucose Controls Levels 1, 2, 3

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

k080641

3. Comparison with predicate:

Comparison Table		
Item	Device	Predicate
Name	AbT Glucose Control	TRUEtest Glucose

Comparison Table		
Item	Device	Predicate
		Control
Number of Levels	3	3
Analyte	Glucose	Glucose
Container	Plastic bottle with dropper-tip	Plastic bottle with dropper-tip
Color	Red	Red
Fill Volume	3.0 mL	3.6 mL
Matrix	Water, D-glucose, buffers, viscosity enhancing agents, salts, dyes, and preservatives	Buffered aqueous solution of D-glucose, a viscosity modifier, preservatives, and other non-reactive ingredients
Intended Use	The AbT Glucose Control Solution is intended for use with TRUEresult™ and TRUE2go™ blood glucose systems using TRUEtest™ test strips. It is used to check their performance.	TRUEtest Glucose Control is a red liquid containing a known amount of glucose. Use Control with TRUE2go™ and TRUEresult™ Meters and TRUEtest™ Test Strips.
Target Population	Prescription and home use	Prescription and home use

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

CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods, Second Edition 08/2004

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 D-glucose used in these controls is traceable to an in-house standard prepared from NIST Standard Reference Material 917b. The control material is analyzed on the sponsor's reference analyzer and recovered values must fall within acceptance criteria based on the target value of the NIST standard.

Expected Values

Glucose controls expected values were determined by repeat analyses using the sponsor's reference clinical chemistry analyzer. Pre-determined acceptance criteria for glucose recovery must be met for each control lot. Acceptable ranges for the glucose values were determined using a TRUEresult monitor and three different lots of TRUEtest strips, ten replicates per strip lot, over three days. Glucose control value ranges are lot dependent and are listed in the control vial label for each lot. Test results must fall within the range printed on the control vial. These ranges may differ from the range printed on the test strip vial.

Stability

Stability characteristics of the AbT Glucose Control Solutions were determined using accelerated shelf-life studies and open vial studies. An unopened shelf-life of 24 months is expected at the recommended storage temperature of 36°F to 86°F. Open vial stability of 90 days was demonstrated when controls were stored at room temperature.

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.