

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

A. 510(k) Number:

k060706

B. Purpose for Submission:

New Device

C. Measurand:

Control material for glucose

D. Type of Test:

Not applicable

E. Applicant:

American Biological Technologies, Inc.

F. Proprietary and Established Names:

Liberty Normal Glucose Control

G. Regulatory Information:

1. Regulation section:

21 CFR§ 862.1660

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):

The Liberty Normal Glucose Control is intended for in vitro diagnostic use (i.e. for external use only) by health care professionals and in the home by people with diabetes mellitus to assess the performance of the Roche Accu-check Active, the Bayer Ascensia Microfill, and the LifeScan OneTouch Ultra and FastTake Blood Glucose Monitors.

2. Indication(s) for use:

See Intended use above.

3. Special conditions for use statement(s):

Over-The Counter Use

4. Special instrument requirements:

For use with Roche Accu-check Active, the Bayer Ascensia Microfill, and the LifeScan OneTouch Ultra and FastTake Blood Glucose Monitors.

I. Device Description:

The Liberty Glucose control contains water, glucose, a viscosity modifier, preservatives, and other non-reactive ingredients. The solution is formulated to act like a whole blood sample. The solution does not contain any human-derived or biological materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

#1--Ascensia Microfill control Solution

#2--Accu-Check Active Control High level

#3--Liberty Glucose Control

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

k023657

k011738

k052980

3. Comparison with predicate:

Similarities		
Item	Device	Predicates
	Liberty Normal Glucose Control	#1-k023657 #2-k011738 #3-k052980
Number of levels	1 level	#1,3 --1 level
Analytes	Glucose	#1,2,3—Glucose
Container	Plastic Bottle with dropper-tip	#1,2,3--Plastic Bottle with dropper-tip
Fill Volume	3.6ml	#3--3.6 ml
Color	Red	#1,2,3—red
Matrix	Buffered aqueous solution of D-Glucose, viscosity modifiers, preservatives and other non-reactive ingredients	#1,2, 3-- Buffered aqueous solution of D-Glucose, viscosity modifiers, preservatives and other non-reactive ingredients
Indications for use	Used to check the performance of Lifescan One-Touch Ultra and Fastake Blood Glucose Monitors, and Accu-check Active, and Ascensia Microfill blood glucose Systems	#1— For use with the Ascensia contour Blood Glucose meter and the Ascensia Microfill Test Strips as a quality control Check #2-- Used to perform quality control checks to ensure that the Accucheck Active System is working properly and that the blood glucose results are reliable
Target Population	Professional and home use	#1,2,3—Professional and home use

Differences		
Item	Device	Predicate
	Liberty Normal Glucose Control	#1-k023657 #2-k011738 #3-k052980
Number of levels	1 level	#2 – 2 levels
Fill volume	3.6ml	#1—2.5ml #2 – 4ml

Differences		
Item	Device	Predicate
Matrix	Buffered aqueous solution of D-Glucose, viscosity modifiers, preservatives and other non-reactive ingredients	#2 Buffered solution containing Glucose, preservative and a thickening agent
Indications for Use	Used to check the performance of Accu-check Active, and Ascensia Microfill blood glucose Systems	#3 Used to check the performance of Medisense Blood Glucose Systems only

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

CLSI EP5-A, Evaluation of the Precision Performance of Quantitative Measurement Methods

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.

The stability of the product was determined by accelerated and real-time stability studies. Accelerated studies were performed at 37, 45 and 56 °C. Using the Arrhenius model, the results indicated shelf life stability for 24 months according to the sponsor's criterion of $\leq 5\%$ loss. Real time studies are on-going to confirm accelerated findings. The open vial stability was determined by testing simulated use of opening vial for 10 minutes then closed. The results indicated open vial stability for 90 days according to the sponsor's criterion of $\leq 5\%$ loss from day 1.

The expected values for the monitors were determined by testing three lots of strips in replicates of 10. The mean, standard deviation and % CV were

obtained for each monitor. Analysis of the data resulted in assigned ranges of the following $\pm\%$ of the calculated mean:

Roche Accu-check Active - $\pm 14.5\%$

Bayer Ascensia Microfill - $\pm 12\%$

LifeScan OneTouch Ultra - $\pm 17\%$

LifeScan FastTake - $\pm 18\%$

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.