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

A. 510(k) Number:

k100747

B. Purpose for Submission:

New glucose control level

C. Measurand:

Quality control material for GlucoSure STAR and Gluco TRACK whole blood glucose monitoring systems

D. Type of Test:

Quality Control Materials

E. Applicant:

Apex BioTechnology Corporation

F. Proprietary and Established Names:

Contrex Plus Low Control Solution

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

   Refer to indications for use below

2. Indication(s) for use:

   The purpose of the control solution test is to validate the performance of the GlucoSure STAR and Gluco TRACK Blood Glucose Monitoring Systems using a test solution with a known range of glucose. A control test that falls within the

acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use

   For over the counter use

4. Special instrument requirements:

   GlucoSure STAR or Gluco TRACK blood glucose monitoring systems

I. Device Description:

The Contrex Plus Low Control solution consists of an aqueous solution of D-glucose. Non-reactive formulation ingredients include: buffers, stabilizer, and preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Gluco Track Blood Glucose Monitoring System (includes glucose control solutions)

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

   k062799

3. Comparison with predicate:

	Candidate Device: **Contrex Plus Low Control Solution**	**Predicate Device:** **Contrex Plus Level 1 and Level 2 Control solutions from Gluco Track Blood Monitoring System (k062799)**
Indications for Use	To check the performance of the GlucoSure STAR and Gluco Track blood glucose monitoring systems	Same
Testing system	GlucoSure STAR & Gluco Track	Gluco Track
Analyte	D-glucose	Same

	Candidate Device: **Contrex Plus Low Control Solution**	**Predicate Device:** **Contrex Plus Level 1 and Level 2 Control solutions from Gluco Track Blood Monitoring System (k062799)**
Matrix	aqueous	Same
Fill volume	2.5 mL	Same
Color	Transparent	Same
Container	Plastic bottle with dropper-tip and white cap	Same but with green cap for Level 1 and blue cap for Level 2
Number of Level(s)	1	2
Target Ranges	(40 - 70 mg/dL)	(87 – 131 mg/dL) (186 – 280 mg/dL)

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

No standard/guidance documents were referenced in this submission.

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 sponsor claims traceability of the D-glucose used in this control to the Glucose Standard Set NERL 1343: 50, 100, 200, and 400 mg/dL.

Expected Values

Glucose control expected values were determined by repeat analyses using the GlucoSure STAR meter, one lot of Contrex Plus Low Control Solution, and 80 GlucoSure STAR test strips. The mean value was 55 mg/dL glucose and a ± 15 mg/dL range was assigned. Value assignment was validated with two GlucoSure STAR meters, one lot of GlucoSure STAR test strips, over 10 days using two strips per test run. Test results must fall within the range printed on the test strip vial. The expected results may change with each new lot. However, the control range is listed on the test strip vial. In the package insert, the user is directed to compare their control result with the range printed on the test strip vial.

The applicant also provides values for the Gluco Track system since this is the same device as the GlucoSure STAR (k073648) except for alternate site testing (AST) claim.

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the Contrex Plus Low Control Solution were determined using real time un-opened and opened vial studies. An unopened shelf-life of 2 years (24 months) is expected at the recommended storage temperature (59°F-86°F). Open vial stability of 90 days (3 months) was demonstrated at the recommended storage temperature of 59°F-86°F. The recommendations in the labeling are to store control solutions at room temperature and additional warnings are given to not freeze or refrigerate control solutions.

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:

Expected values are provided on the test strip vials

N. Proposed Labeling:

The labeling is sufficient and 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.