

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

A. 510(k) Number:

k092645

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for TrueTrack®, TrackEase® and TRURead™ whole blood glucose meters and test strips.

D. Type of Test:

QC Materials

E. Applicant:

Fujirebio

F. Proprietary and Established Names:

FDI Glucose Controls Levels 1, 2, and 3

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	862.1660	Chemistry 75

H. Intended Use:

1. Intended use(s):

Refer to indications for use below

2. Indication(s) for use:

The FDI Glucose Controls are intended 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 TrueTrack®, TrackEASE® and TRUEread™ meters and 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:

TrueTrack®, TrackEASE® and TRUEread™ blood glucose test systems

I. Device Description:

The FDI Glucose Controls consist of three buffered aqueous solutions of D-Glucose, a viscosity modifier, preservatives, red dye, and other non-reactive ingredients. The devices are a non-sterile, over-the-counter product and are intended for external use only. They are non-hazardous and contain no human or animal derived materials. The solutions are packaged in a plastic dropper tipped bottle for easy application to the test strip and contain sufficient volume to run 75 tests. The red dye is included to aid the user to visually confirm application of the control.

J. Substantial Equivalence Information:

1. Predicate device name(s):

TRUEcontrol Glucose Control

2. Predicate 510(k) number(s)

k030703

3. Comparison with predicate

Comparison Table		
Item	Predicate Device (k030703)	Candidate Device
Name	TRUEcontrol Glucose Control	FDI Glucose Controls
Indications for Use	To check the performance of the TrueTrack®, TrackEASE® and TRUEread™ meters and test strips	To check the performance of the TrueTrack®, TrackEASE® and TRUEread™ meters and test strips

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, inorganic salts, amaranth, and preservatives.	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non-reactive ingredients
Target Population	Professional and home use	Professional and home use
Number of Levels	3	3

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

CLSI EP5-A2 Evaluation of Precision Performance of Quantitative Measurement Methods, Second Edition 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 917c. 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 TRURead monitor and three different lots of TRURead test 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. In the labeling, the user is directed to compare their control result with the range on the control vial label.

Stability

Stability characteristics of the FDI 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 - 86°F. Open vial stability of 90 days was demonstrated when controls were stored at room temperature (36°F - 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:

In the labeling the user is directed to compare their control result with the range on the control vial label. For level 1 the glucose values are expected to range from 88-112 mg/dL, for level 2 the values are expected to range from 184 – 242 mg/dL and for level 3 the values are expected to range from 355-456 mg/dL.

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.