

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

A. 510(k) Number:

k110436

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for glucose

D. Type of Test:

Not applicable

E. Applicant:

Fujirebio Diagnostics Inc.

F. Proprietary and Established Names:

FDI Glucose Control Solution for Aviva

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR 862.1660, single (specified) analyte controls	Clinical Chemistry (75)

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 Aviva Blood Glucose Monitor.

3. Special conditions for use statement(s):

For prescription and Over-The-Counter Use

4. Special instrument requirements:

Accu-Chek Aviva Blood Glucose Monitor

I. Device Description:

The FDI Glucose Control is a non-sterile liquid glucose solution that consists of a buffered aqueous solution of D-glucose, a viscosity modifier, preservatives, red dye, and other non-reactive ingredients. The control solution is packaged in a plastic dripper tipped bottle for application of the control solution to the test strip. The red dye is added to the solution to visually confirm the application of the control. Each bottle contains enough solution volume to run 75 tests. This device is a non-sterile, over-the-counter product and is intended for external use only. The solution contains no human or animal derived materials.

J. Substantial Equivalence Information:

1. Predicate device name: Accu-Chek Aviva Control Level 1
2. Predicate 510(k) number(s): k043474
3. Comparison with predicate:

Feature	Candidate Device: FDI Glucose Control Solution	Predicate Device: Accu-Chek Aviva Control Level 1
Intended Use/ Indications for Use	To check the performance of the AccuCheck Aviva Blood Glucose System	Same
Matrix	Aqueous	Same
Analytes	Glucose	Same
Preparation	Liquid, ready-for-use	Same
Fill Volume	2.5 mL	3.6 mL
Number of Levels	1	Same
Target Range (mg/dL)	19-51 (based on a +/- 5% glucose concentration variability lot-to-lot and +/- 15 mg/dL range)	25-55 (derived from the control ranges assigned by the manufacturer)

Packaging	Buffered aqueous solution of D-Glucose, a viscosity modifier, preservatives, and other non reactive ingredients	Glucose, buffer, salts, non-reactive ingredients, preservative, FD & C Blue #1
Target Population	Professional and home use	Same
Storage temperature	Room temperature, between 59°F-86°F (15°C-30°C)	Same

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

CLSI EP-5: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline, Second Edition.

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:

Glucose (0.45 g/L) is added to the control solution. The solution was tested using a commercially available clinical chemistry analyzer against an in-house standard traceable to the NIST Standard reference material 917b. The sponsor states that the 45 mg/dL is produced using SRM917 according to the NIST's "Instructions for Use as a Standard in Clinical Applications" which accompanies the Certificate of Analysis for SRM917.

Value Assignment:

A single lot of control solutions, with an expected value of 45 mg/dL, are tested using a commercially available clinical chemistry analyzer. After this, these control solutions are analyzed using a single AVIVA monitor using three different lots of test strips, 10 replicates per strip lot, over three days. Acceptable ranges are based on pre-determined acceptance criteria established by the manufacturer for glucose recovery for each lot. The glucose control value ranges are lot dependent; therefore the range for each lot is printed on the control solution vial label.

Stability:

Stability characteristics of the FDI Glucose Control Solution for AVIVA were determined by real time and open vial stability studies.

Closed Vial Stability (Real-time/ shelf-life stability)

Shelf Life (real time stability): Control solutions were prepared at a target concentration of 35 mg/dL and were stored at 15-30°C (Control). Samples were periodically removed and tested in triplicate on a commercially available clinical chemistry analyzer. This study supports the claimed shelf life of 24 months when stored at 15-30°C.

Opened Vial Stability

For open vial stability, a number of test and control vials were evaluated for 13 weeks. A target concentration of 35 mg/dL was prepared for each control solution. Each day all vials were opened, allowed to stand for ten minutes, then closed and stored at room temperature. Each week one test group vial was assayed and one control group vial was assayed in triplicate using the ACE Glucose assay. The Control vial was opened on the date of performing the assay and then discarded after testing was complete. The study supports the claimed open vial stability of 90 days when stored at 15 - 30°C.

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 control solution vial labels for each lot.

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.