

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

A. 510(k) Number:

k081478

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for blood glucose monitoring systems - glucose and β -ketone

D. Type of Test:

Not applicable

E. Applicant:

Bionostics Quality Solutions

F. Proprietary and Established Names:

RNA Medical Glucose and β -Ketone Calibration Verification Controls

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 (75)

H. Intended Use:

1. Intended use(s):
RNA Medical Glucose and β -Ketone Calibration Verification Controls are assayed controls intended for use to confirm the calibration and linearity of glucose and β -ketone at the upper and lower limits of the reportable range and at three (3) points within the range. This product is for use with the Precision Xceed Pro™ Blood Glucose and β -Ketone Monitoring System, which uses Precision Xceed Pro™ Blood Glucose Test Strips and Precision Xceed Pro™ β -Ketone Test Strips. It is not for use with the Precision PCx System or the i-STAT 1 Analyzer, which use Precision PCx Test Strips, Precision PCx Plus Test Strips, or i-STAT 1 glucose cartridges. The RNA Medical Glucose and β -Ketone Calibration Verification Controls is intended for use by healthcare professionals.
2. Indication(s) for use:
See intended use section above
3. Special conditions for use statement(s):
For In Vitro Diagnostic Use
For prescription use only

4. Special instrument requirements:

Abbott Diabetes Care Precision Xceed Pro™ Blood Glucose and β-Ketone Monitoring System

I. Device Description:

The RNA Medical Glucose and β-Ketone Calibration Verification Control is a five-level, viscosity-adjusted, aqueous liquid glucose and β-ketone control linearity set optimized for use with the Abbott Diabetes Care Precision Xceed Pro™ Blood Glucose and β-Ketone Monitoring System using Precision Xceed Pro Blood Glucose Test Strips and Precision Xceed Pro Blood β-Ketone Test Strips. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a green color to help users see the solution while dispensing onto a test strip.

J. Substantial Equivalence Information:

1. Predicate device name(s):

RNA GL4 Glucose Calibration Verification Control
Precision Control Solutions

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

k021624; k983504

3. Comparison with predicate:

Characteristic	Predicate Devices		Modified Device
Name:	RNA GL4 Glucose Calibration Verification Control	Precision Control Solutions	RNA Medical Glucose and β-Ketone Calibration Verification Controls
Number of levels:	5 7 vials per kit, only 5 levels for use on specific devices	3	5
Analytes:	Glucose	Glucose, Ketone	Glucose, Ketone
Container:	plastic bottle	plastic bottle	plastic bottle
Fill volume:	4 mL	3 mL	4 mL
Color:	Red	Clear	Green
Matrix:	Buffered aqueous solution of D-Glucose, viscosity modifier, dye, preservative and other non-reactive ingredients.	Buffered aqueous solution of D-Glucose, Beta-hydroxybutyrate and other non-reactive ingredients.	Buffered aqueous solution of D-Glucose, β-hydroxybutyrate, viscosity modifier, dye, preservative and other non-reactive ingredients.

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

- ISO 15197 In-vitro diagnostic test systems – requirements for self-testing in managing diabetes
- ISO 14971 Medical Devices, Application of risk management to medical devices
- ISO 13485 Medical Devices-Quality Management Systems – Requirements for regulatory purposes

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):

No traceability was provided.

Product stability has been established based on real time studies on RNA Medical Glucose and β -Ketone Calibration Verification Controls. Samples are analyzed at predetermined intervals. The protocols for establishing shelf-life and open-vial stability were reviewed and are adequate. The real-time studies support the claimed shelf life, 24 months at room temperature (2°- 30°C) for unopened bottles. The open bottle testing demonstrated a less than 10% change in glucose (all levels) over the 90 day evaluation period. The open bottle testing demonstrated the change in ketone values over the 90 day evaluation met the stability specifications.

The expected values in the labeling are based on multiple determinations performed on randomly selected samples from each lot using several test strip lot numbers and monitors. The assigned values for the reference lots are determined by measurement of all levels of control on each blood glucose meter/strip configuration by Abbott Diabetes Care. Value assignment for each lot of control solution will be provided in the package insert delivered with the control.

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.