SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k123851

B. Purpose for Submission:

New device

C. Measurand:

Glucose

D. Type of Test:

Quality Control Solution

E. Applicant:

Bionostics, Inc.

F. Proprietary and Established Names:

Glucose Meter-Check® Solution for Roche ACCU-CHEK

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1660, Quality Control Material

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):

   See indication for use below

2. Indication(s) for use:

   Glucose Meter-Check Solution Roche ACCU-CHEK is intended to assess the performance of the following Roche ACCU-CHEK blood glucose monitoring systems:

   •Roche ACCU-CHEK Nano SmartView® using SmartView® test strips
   •Roche ACCU-CHEK Aviva® and ACCU-CHEK Aviva Combo® using Aviva Plus® test strips
   •Roche ACCU-CHEK Active® using ACCU-CHEK Active test strips
   •Roche ACCU-CHEK Compact® and ACCU-CHEK Compact Plus® using ACCU-CHEK Compact test strips.
   •Roche ACCU-CHEK Advantage using Comfort Curve® test strips

   Glucose Meter-Check Solution for Roche ACCU-CHEK is intended for use by healthcare professionals and people with diabetes mellitus at home.

3. Special conditions for use statement(s):

   For *in vitro* diagnostic use only

4. Special instrument requirements:

   This control solution will be labeled and distributed for use with Roche ACCU-CHEK Blood Glucose Test Systems.

I. Device Description:

Glucose Meter-Check Solution is a single-level, viscosity-adjusted, aqueous liquid glucose control solution. Glucose Meter-Check Solution is intended for use to verify the performance of the Roche ACCU-CHEK brand BGM Systems listed in the package insert at recover glucose values within the interval 2 recommended in ISO 15197:2003 In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus for most meter types (Aviva, SmartView, Advantage), and comparable to solutions currently marketed by Roche for others (Active, Compact). This mid-level glucose concentration will complement the current, low and high glucose concentrations available in quality control products distributed by Roche Diagnostics for these same BGM systems. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip.

Glucose Meter-Check Solution is a non-hazardous aqueous solution glucose control solution containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Glucose Meter-Check Solution for Roche ACCU-CHECK BGMS

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

   k081403

3. Comparison with predicate:

   Table 1. Similarities and differences between candidate and predicate device.

Similarities and Differences of the Blood Glucose Control				
Item	Predicate Device Glucose Meter-Check Solution for Roche ACCU-CHECK BGMS K081403		Candidate Device Same K123851	
Intended Use/Indications for Use	Glucose Meter-Check® for Roche is intended for in vitro diagnostic use to assess the performance of the Roche ACCU-CHEK blood glucose test systems: Aviva, Active, Advantage and Compact and Compact Plus by healthcare professionals and in the home by people with diabetes mellitus.		Same, with the addition of ACCU-CHEK Nano	
Stability	24 Months		same	
Value assignment	determined by analysis of glucose on commercial lots of glucose test strips qualified for proper measurement using manufacturer recommended control solution		same	
Traceability	N.I.S.T. SRM 917		same	
Target range	83 – 110 mg/dL (range of midpoint assigned values with various BGMS)		106 – 176 mg/dL (range of midpoint assigned values with various BGMS)	
Auto QC detection	no		yes, for AVIVA and Nano	
Matrix	Ingredient	Concentration (w/v%)	Ingredient	Concentration (w/v%)
	High Purity Water	91.6	High Purity Water	88.6
	Buffers	1.0	Buffers	same
	Salts	0.5	Salts	3.5
	Viscosity Modifier	6.6	Viscosity Modifier	same
	Glucose	0.10	Glucose	0.12
	Preservatives	0.05	Preservatives	same
	Dye	0.08	Dye	same
Container	6 mL white LDPE		same	
Analyte	glucose		same	
Color	red		same	
Net Fill	4 mL		same	

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

- •ISO 15197:2003 In Vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.
- •ISO 14971:2007 Medical devices – Application of risk management to medical devices
- •ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
- •ISO 18113-4 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 4: In vitro diagnostic reagents for self-testing EN 13640 Stability Testing of In Vitro Diagnostic Reagents
- •Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

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 Glucose Meter-Check Solution for Roche ACCU-CHEK is traceable to NIST SRM 917.

Value Assignment:

Value assignment for each production lot of control solution is determined by analysis of glucose on commercial lots of glucose test strips qualified for proper measurement using manufacturer recommended control solution. Each meter and strip combination is considered to be operating correctly if all measurements of Roche ACCU-CHEK branded control solutions are recovered within the assay ranges provided on each carton of test strips. Value assignment range is determined as the mean value of all measurements ± 15% of the mean value.

Stability:

Product stability has been established based on real time studies. The studies performed showed that the control materials remained within specification to support the sponsor's claims of stability.

(1) Transport Stability (closed). Testing demonstrated less than 5% change in glucose concentration over a 10 day period, under extreme temperature conditions.

(2) Open-Vial Stability: Testing demonstrated less than 5% change in glucose concentration over the 90 day evaluation period.

(3) Closed-Vial Stability: Testing demonstrated less than 10% change in glucose concentration over 24 months at 30°C.

d. Matrix effect:

Not applicable

e. Detection limit:

Not applicable

f. Analytical specificity:

Not applicable

g. Assay cut-off:

Not applicable

2. Comparison studies:

Not applicable

3. Clinical studies:

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:
An expected range for each glucose monitoring system is printed in the labeling. When using this control material, users are to compare their control results to the range printed in the labeling for the system being used rather than the range printed on the test strip.

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.