

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

A. 510(k) Number:

k081403

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for blood glucose monitoring systems

D. Type of Test:

Not applicable

E. Applicant:

Bionostics Quality Solutions

F. Proprietary and Established Names:

Glucose Meter-Check Control Solution for Roche ACCU-CHEK

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1660 Quality control material (assayed and unassayed)

2. Classification:

Class I

3. Product code:

JJX, single (specified) analyte controls (assayed and unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

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

- Roche ACCU-CHEK Advantage using Comfort Curve® test strips
- Roche ACCU-CHEK Active®
- Roche ACCU-CHEK Aviva®
- Roche ACCU-CHEK Compact® and ACCU - CHEK Compact Plus®

The Meter Check Control Solution is intended for use by healthcare professionals and people with diabetes mellitus at home. For *In Vitro* diagnostic use.

2. Indication(s) for use:

See intended use section above.

3. Special conditions for use statement(s):
Over-The-Counter Use

4. Special instrument requirements:

Roche ACCU-CHEK Advantage using Comfort Curve® test strips
Roche ACCU-CHEK Active®
Roche ACCU-CHEK Aviva®
Roche ACCU-CHEK Compact® and ACCU - CHEK Compact Plus®

I. Device Description:

Glucose Meter-Check™ Control Solution is a single-level, viscosity-adjusted, aqueous liquid glucose control solution. **Glucose Meter-Check™ Control Solution** is intended for use to verify the performance of the Roche ACCU-CHEK brand blood glucose monitoring systems listed in the package insert at glucose levels within the normal fasting blood glucose range for non-diabetic persons. 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Accu-Chek AVIV, ACTIVE, ADVANTAGE, COMPACT Control, SMS Glucose Control
2. Predicate 510(k) number(s):
k043474, k012324, k032552, k022171, k070506
3. Comparison with predicate:

Product	Glucose Meter-Check Solution	Accu-Chek AVIVA Control	Accu-Chek ACTIVE Control	Accu-Chek ADVANTAGE Control	Accu-Chek COMPACT Control	SMS Glucose Control
510(k), Date		K043474 04.27.05	K012324 12.05.01	K032552 09.12.03	K022171 07.23.02	K070506 04.18.07
Net Fill	4 mL	2.5 mL	4 mL	4 mL	3 mL	3.6 mL
Color	red	blue	clear	blue	dark blue	red
Analyte	glucose	glucose	glucose	glucose	glucose	glucose
Container	plastic vial	plastic vial	plastic vial	plastic vial	plastic vial	plastic vial
Matrix	aqueous	aqueous	aqueous	aqueous	aqueous	aqueous
Level	normal	low high	low high	low high	low high	normal
Mid Assigned Range*	107	40 300	54 173	61 342	83 410	169

*Mid Assigned Range is mean of assigned ranges for each meter (Accu-Chek ACTIVE for Glucose Meter-Check and SMS Glucose Control)

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

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):

A reference lot of material is used to establish the targeted glucose value on the YSI 2300. Value assignment for subsequent lots is compared to the reference lot and is acceptable if within a specified range of values. After verifying that the meters and test strips are recovering within target ranges on the Roche-branded control solutions appropriate for each meter type, multiple samples of the Glucose Meter-Check solution are analyzed on each of 2 meters on each of 3 lots of test strips. Value assignment range is determined as the mean value of all measurements $\pm 15\%$ of the mean value.

Product stability has been established based on real time and accelerated studies on products with equivalent formulation matrixes and packaging. Samples are analyzed at predetermined intervals with failure defined by the sponsor as $\leq 95\%$ recovery of the most labile analyte, glucose.

Close Bottle: In these evaluations, the change in glucose concentration over 24 months at 31 °C is less than 5%. Ongoing real-time studies continue under refrigerated, room and elevated temperature conditions to establish final product stability and to ensure performance to within specified tolerances over labeled shelf life.

Open Bottle: This testing demonstrated less than 5% change in glucose over the 90 day evaluation period.

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:

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.