

**SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k112352

B. Purpose for Submission:

New device

C. Measurand:

Glucose

D. Type of Test:

Not Applicable

E. Applicant:

Bionostics, Inc.

F. Proprietary and Established Names:

Glucose Meter-Check Control Solutions level 1&2 for NIPRO TRUEresult Glucose Monitoring System

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 Control Solution for NIPRO TRUEresult is intended for use to verify the performance and correct operation of the NIPRO TRUEresult Glucose Test Systems. Glucose Meter-Check Control Solution for NIPRO TRUEresult 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 TRUEresult Blood Glucose Test Systems only manufactured by NIPRO Diagnostics.

I. Device Description:

Glucose Meter-Check Control Solution for NIPRO TRUEresult is a buffered, viscosity adjusted, aqueous solution with glucose containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation. The Glucose Meter-Check Control Solution is formulated for NIPRO TRUEresult glucose meters. The product is provided in 2 levels, Glucose Meter-Check Solution Level 1 and Glucose Meter-Check Solution Level 2 .

J. Substantial Equivalence Information:

1. Predicate device name(s):

TRUEtest Control Solution (*for use with TRUEresult BGM*)

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

k080641

3. Comparison with predicate:

Items	Glucose Meter-Check Control Solution for NIPRO TRUEresult (Candidate Device)	TRUEtest Control Solution (Predicate Device)
Similarity		
Intended Use	Glucose Meter-Check Control Solution for NIPRO TRUEresult is intended for use to verify the performance and correct operation of the NIPRO TRUEresult Glucose Test Systems.	Same
Levels per Kit	Same	Two
Analytes	Same	Glucose
Container	Same	6 mL LDPE vial with dispensing tip and cap
Volume	Same	4 ml
Solution Color	Same	Red
Matrix	Same	Buffered, aqueous solution of D-Glucose, viscosity modifier, Preservatives and other non-reactive ingredients.
Difference		
Ingredients	The device lacks the proprietary ingredients so it won't be identified automatically as a control.	The device contains certain proprietary ingredients which allow the glucose monitor to recognize the solution as a control.

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

1. ISO 18113-4 In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) ... for self testing
2. EN13640: Stability Testing of In Vitro Diagnostic Reagents

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:

New lots of material are verified to ensure the trueness of measurement are equivalent to prior lot of the same material ($\pm 3\%$) using YSI 2300 or equivalent calibrated with solutions provided by YSI traceable to NIST SRM 917.

Value Assignment:

The analytical values for each production lot of material are confirmed by comparison of new production lots of material to the Reference Lot of product with the same formulation in parallel measurement on the YSI 2300 reference method in order to maintain lot-to-lot variability within close tolerances.

Value assignment for each production lot of control solution was conducted with both types (NIPRO or Liberty) of current version blood glucose meters, test strips and quality control solutions purchased through retail outlets. Briefly, three lots of test strips for each meter/strip type combination are evaluated following the following sequence:

- (1) Five measurements of control solution distributed with each meter (NIPRO or Liberty branded) on each of two meters to qualify the meters and test strip lots or use. All measurement values must fall within value assignment provided by the manufacturer for the control solution printed on the test strip vials (total 30 measurements).
- (2) Ten measurements of the Glucose Meter-Check Solution on each of two meters, on each of the three lots of test strips (total 60 measurements).
- (3) Value assignment for Glucose Meter-Check Control Solution for NIPRO TRUEresult is determined as the mean of all measurements on all meters and test strips ± 15 mg/dL (Level 1) and $\pm 17\%$ of the mean value (Level 2), providing a single acceptable value range for all test strips.

Acceptance criteria: Resulting value assignment is deemed acceptable if $> 95\%$ of all individual measurements values fall within the range of acceptable values determined by this method.

For each released lot, $> 95\%$ (100%) of all measurements of Meter-Check control Level 1 and Level 2 were found to be within these limits and therefore, the acceptance criteria are met. The results of a representative value assignment protocol are presented in the table below:

Control Level	Meter Brand	Test Strip Brand	Control Brand (Level)	Pooled Mean	Pooled SD	Pooled CV%	Within Limits
Low (1)	NIPRO TRUEresult	TRUEtest	TRUEtest (1)	47.0	0.7	1.6%	100.0%
			MeterCheck (1)	47.7	0.7	1.5%	100.0%
	Liberty Blood Glucose Monitor	Liberty	Liberty (1)	47.6	1.0	2.1%	100.0%
			MeterCheck (1)	47.5	1.0	2.1%	100.0%
Mid (2)	NIPRO TRUEresult	TRUEtest	TRUEtest (2)	116.7	2.7	2.3%	100.0%
			MeterCheck (2)	118.0	2.6	2.2%	100.0%
	Liberty Blood Glucose Monitor	Liberty	Liberty (2)	114.2	1.8	1.6%	98.0%
			MeterCheck (2)	116.3	4.3	3.7%	100.0%

The acceptable range is printed on the control solution vial label. The package insert clearly instructs users to always compare their result to the range printed on the control solution vial, not on the test strip vial label.

Stability:

Product stability has been established based on real time studies.

- (1) Open-Vial Stability: Acceptable performance (4-30 °C storage after opening at the end of 90-days) is determined as less than 10% change in glucose concentration in product stored at 30°C as measured by YSI 2300 against reference material of the same product stored at 2-8 °C. Product is opened and 5-7 drops dispensed weekly during this period to simulate heavy use.
- (2) Closed-Vial Stability: Acceptable performance (4-30 °C storage at the end of twenty-four months) is determined as less than 10% change in glucose concentration in product stored at 30°C as measured by YSI 2300 against reference material stored at 2-8 °C
- (3) Transport Stability: Acceptable performance (product should withstand ≤ -10 °C for at least 5 days followed by at least 5 days at +45 °C following the freeze/thaw cycle) is determined as less than 10% change in glucose concentration in product stored at 30°C after freeze/thaw as measured by YSI 2300 against reference material stored at 2-8 °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:

Not applicable

N. Proposed Labeling:

The following warning is displayed in the warning and precaution section of the labeling to mitigate the risk of misuse and misinterpretation of the control solutions:

IMPORTANT: The result of a control test with this solution is NOT automatically marked as a control solution test.

PLEASE NOTE: When using this control material on the NIPRO TRUEresult Blood Glucose Meter, the control results can not be differentiated from the patient's results and therefore will be incorporated into the calculation of the patient's average glucose concentration.

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.