

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k062538

B. Purpose for Submission:

New device

C. Measurand:

Whole blood Glucose

D. Type of Test:

Quantitative, utilizing Glucose Oxidase technology

E. Applicant:

Diacare Corporation

F. Proprietary and Established Names:

EASY CHECK Blood Glucose Monitoring System
EASY CHECK Glucose Control Solution

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose Test System
21 CFR 862.1660, Quality Control material (assayed and unassayed)

2. Classification:

Class II (reagent) and Class I, reserved (controls)

3. Product code:

NBW, System Test, Blood Glucose, Over the Counter
CGA, Glucose Oxidase, Glucose
JJX, Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

75 (Chemistry)

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

The EASY CHECK Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm and the forearm. It is intended for use by healthcare professionals and people with diabetes mellitus at home and in healthcare facilities as an aid in monitoring the effectiveness of diabetes control programs. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The Easy Check Control Solution is intended for *in vitro* diagnostic use by healthcare professionals and in the home by people with diabetes mellitus to assess the performance of the EASY CHECK Blood Glucose Monitoring System.

3. Special conditions for use statement(s):

For professionals and over-the-counter use.

Not for neonatal use.

The alternative site testing (palm and forearm) in the EASY CHECK Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

4. Special instrument requirements:

EASY CHECK Blood Glucose Meter

I. Device Description:

The EASY CHECK Blood Glucose Monitoring System contains the following:

1. EASY CHECK Blood Glucose Meter
2. EASY CHECK Control Solution (2 levels)
3. EASY CHECK Blood Glucose Test Strips
4. 3-Volt Lithium Coin Battery
5. User's Guide
6. Getting Started Manual

- 7. Log book
- 8. Lancets
- 9. Code Card

The EASY CHECK Glucose Control Solution comes in two levels (Lo and High) and is made of an aqueous buffer consisting of glucose, sodium benzoate, a viscosity modifier and a non-reactive ingredient.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Elite Diabetes Care System

Bayer Ascensia Microfill Control

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

k043311, k023657

3. Comparison with predicate:

Similarities and Differences of the Blood Glucose System		
Item	EASY CHECK Glucose Meter (Candidate device)	Bayer Elite Glucose Meter (Predicate device)
Detection method	Amperometry	Same
Enzyme	Glucose oxidase	Same
Mediator	Potassium ferricyanide	Same
Electrode	Carbon	Same
Coding	Code key	Same
Sample type	Whole blood	Same
Humidity range	20-80%	Same
Power supply	3V lithium battery (CR2032)	Same
Battery lifetime	Over 1000 tests	Same
Test range	30-600 mg/dL	20-600 mg/dL
Hematocrit range	30-50%	20-60%
Test time	9 seconds	30 seconds
Sample volume	1.5 uL	3 uL
Temperature range	2-30 ⁰ C	15-30 ⁰ C
Test sample	Fingertip, palm and forearm	Fingertip
Memory capability	180 sets	20 sets
Battery life	Approx. 1000 tests	Approx. 4000 tests
Size L x W x H (cm)	58x80x19 mm	81x51x14 mm
Weight	50g (without batteries)	same

Similarities and Differences of the control solution		
Item	EASY CHECK Glucose Control Solution (Candidate device)	Bayer Ascensia Microfill Control Solution (Predicate device)
Indication for use	Used to check the performance of EASY CHECK Blood Glucose Monitoring System that the blood glucose result is reliable	For use with the Ascensia Contour Blood Glucose Meter and the Ascensia MICROFILL Test Strips as a quality control check.
Analyte	Glucose	Same
Number of levels	2	1
Container	Plastic bottle with dropper tip	Same
Color	Red	Same
Temperature range	2-30 ⁰ C (36-86 ⁰ F)	Same
Fill volume	2.5 mL	Same
Matrix	Aqueous buffer consisting of glucose, sodium benzoate, a viscosity modifier and a non-reactive ingredient.	Same
Target population	Professional and home use	Same

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

1. CLSI EP5-A, *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.*
2. CLSI EP6-P2, *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline.*
3. CLSI EP7-P, *Interference Testing in Clinical Chemistry; Proposed Guideline*
4. CLSI EP9-A2 *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Second edition*
5. ISO 15197:2003, *In Vitro Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Test Systems for Self Managing Diabetes Mellitus*

L. Test Principle:

The Test Principal of this device is based on amperometric technology using glucose oxidase. When the blood sample is applied to the test strip, electrons are formed by the reaction between glucose oxidase and blood glucose. The electrical current is measured by the meter and correlates with the concentration of glucose in the blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Two different lots of EASY CHECK Blood Glucose Test Strips were tested to assess the precision and repeatability of the EASY CHECK Blood Glucose Monitoring System using venous whole blood concentrations between 30 and 335 mg/dL (spiked samples). Blood samples were collected from healthy donors into tubes that contained heparin. Ten different meters were tested for 20 days with 2 runs per day. The coefficient of variation for one lot of the test strips is shown below:

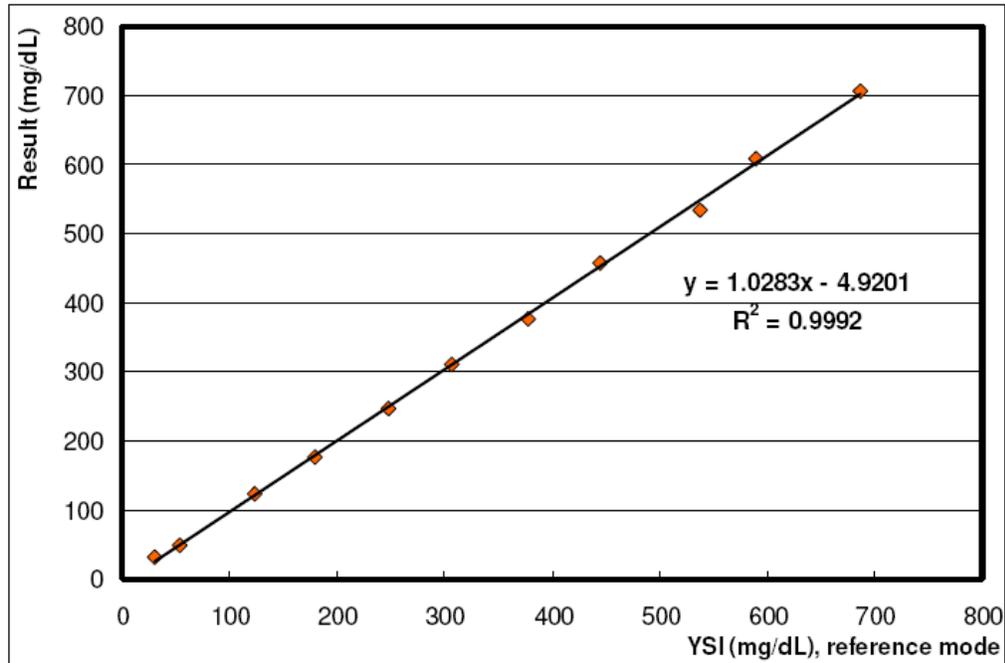
Precision table:

Level	Mean (mg/dL)	SD (Within-run)	SD (Between-run)	% CV
1	32	2.7	1.5	6.4
2	49	2.8	1.4	6.8
3	71	2.8	2.0	5.3
4	113	2.7	2.6	4.4
5	216	5.6	1.9	3.8
6	335	7.1	4.2	3.7

b. *Linearity/assay reportable range:*

A linearity study was performed using oxygenated venous blood supplemented with 50% aqueous glucose solution to provide samples at eleven different blood glucose levels (25-35 mg/dL, 40-60 mg/dL, 120-130 mg/dL, 180-190 mg/dL, 240-250 mg/dL, 300-320 mg/dL, 370-390 mg/dL, 450-470 mg/dL, 520-540 mg/dL, 600-620 mg/dL, and 670-750 mg/dL). Two glucose meters and two different lots of test strips were used and ran in duplicate. YSI glucose analyzer as a standard reference instrument was used for validation. The linear regression was as follows:

$$y = 1.0283x - 4.9201, r^2 = 0.992.$$



The sponsor claimed that the linearity range of the EASY CHECK Blood Glucose Monitoring System is 30 to 600 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

There is no calibration required to perform the EASY CHECK Blood Glucose Monitoring System test; however, a lot specific code card is provided with each box of the EASY CHECK glucose test strips. Calibrations were done in-house and parameters were coded into the code card. The user must check and make sure that the code number printed on the code card matches the code number on the test strip vial and that it also matches the code number in the EASY CHECK glucose meter before testing.

The EASY CHECK Blood Glucose Monitoring System is traceable to NIST SRM 917b reference material.

The value assignment of the EASY CHECK Glucose Control Solutions was determined by an in-house procedure. The range of the control solutions was determined by running multiple runs of the control solutions on the EASY CHECK glucose meters. For control solution level 1, range was set at mean ± 25% of the average value. For control solution level 2, range was set at mean ± 20% of the average value.

Accelerated stability and real time stability of the EASY CHECK Glucose Control Solutions were performed to assess the shelf-life and open-vial stability of the EASY CHECK glucose control solutions, respectively. The sponsor claimed that the shelf-life of the EASY CHECK glucose control

solutions is 12 months when stored at 2-30⁰C and the open-vial stability is 60 days after opening when stored at 2-30⁰C.

EASY CHECK glucose test strips shelf-life is 18 months and open-vial stability is 60 days after opening when stored at 2-30⁰C.

d. Detection limit:

See Precision at 32 mg/dL and linearity/reportable range studies above.

e. Analytical specificity:

i.) An interference study was conducted to determine the effect of select endogenous and exogenous substances. The following 7 exogenous and 3 endogenous substances were tested: acetaminophen, ascorbic acid, dopamine, ibuprofen, L-Dopa, tetracycline, tolutamide, cholesterol, creatinine and uric acid. Stock solutions of the above chemicals were prepared and spiked into the tested pool sample with different concentrations. The % bias was calculated based on the differences between the spiked sample and the control pool sample. The sponsor claimed a bias of $\leq 16\%$ for all the interferents tested.

The sponsor claimed that the therapeutic levels of L-dopa or dopamine may result in inaccurate glucose readings with the system. Interference was also observed in samples with high ascorbic acid and uric acid. This information is also provided in the limitation section of the package insert.

ii.) A hematocrit study was performed to evaluate the hematocrit variation effect of the EASY CHECK Blood Glucose Monitoring System. Oxygenated venous blood sample with 9 different Hct levels (20, 25, 30, 40, 50, 55, 60, 65, 70%) were prepared. Five different glucose concentrations of oxygenated venous blood concentrations (30, 70, 150, 260, 600 mg/dL) were prepared. The data showed that hematocrit levels outside of 30%-50% range may cause inaccurate test results.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device and reference method:

Two hundred sixty people with diabetes performed a fingerstick test using the EASY CHECK Blood Glucose System. A healthcare professional then performed the test on the EASY CHECK Blood Glucose System, the Bayer

System (predicate device) and the YSI analyzer (reference method). The range of glucose values for these samples was 30-505 mg/dL (YSI). The linear regressions were as follows:

Patient's results on EASY CHECK (Y) vs YSI (X):

$$Y = 0.9681X + 5.6043, r^2 = 0.9734$$

Healthcare professional's results on EASY CHECK (Y) vs YSI (X):

$$Y = 0.9643X + 5.7915, r^2 = 0.9782$$

Based on the ISO Standard 15197 document, how well the EASY CHECK Blood Glucose Monitoring System compared with the laboratory method was shown in the table below:

For glucose results lower than 75 mg/dL, the percent (and number) of meter results that match the laboratory method within 15 mg/dL:	(33/33) 100%
For glucose results at or higher than 75 mg/dL, the percent (and number) of meter results that match the laboratory method within 20%:	(215/227) 95%

Note: When meter results are compared to the laboratory results, results below 75 mg/dL are compared in mg/dL.

b. Matrix comparison:

Alternative testing sites : palm and forearm testing has been performed by the patients and the healthcare professionals to show comparable performance at times of steady state conditions with regard to accuracy at the finger site in comparison to the YSI (reference method). The range of glucose values for these samples was 30-525 mg/dL (by the finger). The linear regressions were as follows:

Patient's palm (Y) vs patient's finger (X):

$$Y = 0.9921X + 5.371, r^2 = 0.9784$$

Patient's forearm (Y) vs patient's finger (X):

$$Y = 0.9576X + 5.2861, r^2 = 0.9697$$

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):

See section 2a above.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose levels for people without diabetes (referenced from Joslin Diabetes Manual):

Time	Range (mg/dL)	Range (mmol/L)
before breakfast	70-105	3.9-5.8
before lunch or dinner	70-110	3.9-6.1
one hour after meals	less than 160	less than 8.9
two hours after meals	less than 120	less than 6.7
between 2 and 4 AM	greater than 70	greater than 3.9

N. Instrument Name:

EASY CHECK Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

The EASY CHECK Blood Glucose Meter used with the EASY CHECK Glucose Test Strips is a single use test system used to quantitatively measure blood glucose in fresh capillary whole blood from the finger and from the following alternative sites: the palm and the forearm. The EASY CHECK Glucose Test Strips are for *in vitro* diagnostic use only. The EASY CHECK Blood Glucose Meter is not intended for use with neonates.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes or No

3. Specimen Identification:

The EASY CHECK Blood Glucose Monitoring System's memory will store 180 test results with respective dates and time.

4. Specimen Sampling and Handling:

Testing on Fingertips – Refer to the EASY CHECK Blood Glucose Monitoring System User's Guide for detailed meter information prior to testing. Items needed: EASY CHECK Blood Glucose Meter, lancet, and EASY CHECK Glucose Test Strips.

Testing on palm and forearms- The following important notes are listed in the package insert:

- Consult your healthcare professional before you begin using the palm or forearm for testing.
- Under certain conditions, blood glucose test results obtained using samples taken from your palm or forearm may differ significantly from fingertip samples. Do not use palm or forearm testing when your blood glucose is changing rapidly such as following a meal, an insulin dose, or associated with physical exercise.

5. Calibration:

Lot Specific adjusted calibration with pre-set test strip code number.

6. Quality Control:

Two levels of control solutions are provided by the sponsor.

To Run Glucose Control Solution Test:

The EASY CHECK Glucose Control Solutions are used as a quality control check to make sure that the EASY CHECK Blood Glucose Meter and the EASY CHECK Glucose Test Strips are working correctly. Each EASY CHECK Glucose Control Solution is intended for use only with the EASY CHECK Glucose Test Strips. A control solution test is performed the same way that a blood glucose test is performed except control solution is used in place of a blood drop. The control solution test confirms that the meter and test strips are working correctly. The control solution test results should fall within the range of results printed on the vial label of the control.

Each EASY CHECK Glucose Control Solution should produce results that fall within the range of results printed on the vial label of the control being used. If the control solution test result is outside the range (is either higher or lower), the EASY CHECK Glucose Meter and test strip may not be working as a system.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:

1. Humidity testing was performed and the sponsor claimed that the EASY CHECK BGMS is not affected by humidity between 20% to 80%.
2. Glucose meter operating temperature was evaluated and the sponsor claimed that the EASY CHECK BGMS can get the same acceptable reading from 10⁰C to 40⁰C.
3. Glucose meter storage temperature was evaluated and the sponsor claimed that the EASY CHECK glucose meter can be stored between -20⁰C to 50⁰C.
4. A sample volume sensitivity study was performed and the sponsor claimed that there is no significant bias for sample volumes between 0.5 µL to 1.5 µL.
5. Altitude testing was not performed; therefore, the sponsor has a limitation that the system can only be used at sea-level in the package insert.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.