

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

A. 510(k) Number:

k082683

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative-glucose oxidase

E. Applicant:

Standard Diagnostics

F. Proprietary and Established Names:

Standard Diagnostics SD Check Gold BGMS

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1345, Glucose test system

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

2. Classification:

Class II

Class I, reserved

3. Product code:

NBW – System, Test, Blood Glucose, Over the Counter

CGA - Glucose Oxidase, Glucose

JJX - Quality Control Material (Assayed and Unassayed)

4. Panel:

Chemistry 75

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The SD CHECK GOLD blood glucose monitoring system is indicated for monitoring glucose in fresh capillary whole blood samples drawn from the fingertip, palm, forearm or upper arm. SD CHECK GOLD meter must be used with SD CHECK GOLD blood glucose test strip and SD CHECK GOLD control solutions.

The SD Check Gold control solutions Level M and Level H are for use with SD Check Gold test system as quality controls to verify the accuracy of blood glucose test results.

Testing is done outside the body (in vitro diagnostic use). This system is indicated for home (over-the-counter: OTC) by persons with diabetes, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control.

This system should not be used for the screening or diagnosis of diabetes or for testing newborns.

3. Special conditions for use statement(s):

For over the counter use

Not for use in the screening or diagnosis of diabetes

Not for use in testing newborns

Not for use on critically ill patients, dehydrated patients, patients in shock, or hyperosmolar patients

4. Special instrument requirements:

SD Check Gold test strips must be used with the SD Check Gold blood glucose meter

I. Device Description:

The SD Check Gold Blood Glucose Monitoring System consists of glucose meter, blood glucose test strips and two levels of control solution, Level M (mid) and H (high).

J. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Accu-Chek Advantage System
2. Predicate 510(k) number(s):
k032552
3. Comparison with predicate:

Similarities		
Item	SD Check Gold	Predicate
Indications for Use	As an aid to monitor the effectiveness of diabetes control, for over the counter use.	Same
Measurement range	20 to 600 mg/dL	Same
Test principle	Amperometric	Same
Enzyme/assay	Glucose oxidase	Same

Differences		
Item	Device	Predicate
Altitude	Up to 11,351 feet	Up to 10,151 feet

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

ISO 15197: In vitro diagnostic test systems - Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus - 2003

L. Test Principle:

Capillary whole blood is applied to the SD Check Gold test strip containing the enzyme glucose oxidase. A voltage is applied and the glucose concentration is calculated from the electrical current. The result is then shown on the meter display. The meters are calibrated to display plasma equivalent results.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

The repeatability was evaluated with one lot of test strips and ten (10) glucose meters. Venous blood samples at five glucose concentrations were measured 10 times each.

Blood Concentration	Mean (mg/dL)	SD	CV (%)
30-50 mg/dL	44.2	1.1	2.4
51-110 mg/dL	82.8	1.9	2.3
111-150 mg/dL	144.9	3.5	2.4
151-250 mg/dL	225.8	5.1	2.3
251-400 mg/dL	337.2	8.3	2.5

The intermediate precision was evaluated with one lot of test strips and ten (10) glucose meters. Quality control material at three glucose concentrations was measured once a day for ten days.

Quality Control	Mean (mg/dL)	SD	CV (%)
Low ~40 mg/dL	41	1.7	4.1
Mid ~125 mg/dL	128	2.8	2.2
High 340 mg/dL	345	8.8	2.6

b. Linearity/assay reportable range:

The linearity was evaluated with three glucose meters using blood samples at seven (7) glucose concentrations. The glucose samples were prepared from venous blood samples containing heparin anticoagulant at approximately 40% hematocrit. The range of glucose concentrations used was 5 to 720 mg/dL and the sponsor performed these studies using a version of the meter with the Hi and Lo glucose concentration flags disabled.

The results of meter readings vs. YSI Plasma Values were compared using linear regression analysis and are summarized in the table below:

Meter	Slope	Intercept	R	R2
1	0.982	0.127	0.9997	0.9994
2	0.978	-0.684	0.9997	0.9995
3	0.979	-1.141	0.9998	0.9996

Results equal to or below 20 mg/dL are reported as “Lo” and results greater than or equal to 600 mg/dL reported as “Hi.” The measuring range is from 20 to 600 mg/dL.

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

The test system was compared to the YSI. See the method comparison section 2 below.

Stability characteristics of the test strips were determined using real-time unopened and open-vial studies. When stored at the recommended storage temperature of 36° F to 90°F the unopened shelf-life is 18 months and once opened, the test strips are stable for up to 3 months.

Stability characteristics of the control solutions were determined using real-time unopened and open-vial studies. The unopened shelf-life is 24 months at the recommended storage of 46° F to 86°F. Once opened, the control solutions are stable for 3 months when stored at 46° F to 86°F.

d. Detection limit:

See linearity 1.b. above.

e. Analytical specificity:

Hematocrit:

The effect of different hematocrit levels was evaluated with one test strip lot and five glucose meters and using blood samples at five glucose concentrations (50, 160, 275, 390 and 500 mg/dL). The glucose samples were prepared from venous blood containing heparin anticoagulant at five different hematocrit levels ranging from 15-65%. Glucose results for each concentration and hematocrit level were compared to the same samples tested on the YSI reference method. Additionally, the samples at 15, 20, 60, and 65% hematocrit were compared to samples with 40% hematocrit using the same SD Check Gold meter.

Samples with 20% and 60% hematocrit tested on the SD Check Gold meter were within +/-15% of the same sample tested on YSI and the 40% hematocrit sample. The sponsor claims an acceptable hematocrit range of 20 to 60%.

Endogenous compounds and drugs:

The sponsor evaluated the interference from different concentrations of the substances listed below. Three glucose levels were tested for each interferant, 70 mg/dL, 100 mg/dL and 300 mg/dL. The sponsor defined interference as when the test sample containing interferant does not recover within +/-10% of the control sample without interferant.

Studies demonstrated that all the interfering substances listed below did not significantly interfere with the glucose readings.

Interferant tested	Concentration
Acetaminophen	6 mg/dL
Ascorbic acid (Vit. C)	4 mg/dL
Bilirubin	40 mg/dL
Uric acid	9 mg/dL
Triglyceride (T.G)	1026 mg/dL
Total Cholesterol	506 mg/dL
Acetyl-salicylic acid	120 mg/dL
Ibuprofen	50 mg/dL
Fructose	15 mg/dL
Galactose	60 mg/dL
Tetracycline	5 mg/dL
Tolbutamide	4 mg/dL
Dopamine	5 mg/dL
Methyl-dopa	2 mg/dL
Creatinine	30 mg/dL
Urea	500 mg/dL
Tolazamide	8.4 mg/dL
Warfarin	1 mg/dL
Levodopa	4 mg/dL
Sodium fluoride	200 mg/dL
Maltotetraose	120 mg/dL
Mannose	5 mg/dL
Lactose	25 mg/dL
Mannitol	800 mg/dL
Sorbitol	10 mg/dL
Xylitol	25 mg/dL
Maltotriose	240 mg/dL

Warfarin at concentrations greater than 1 mg/dL affects the accuracy of the test and a warning appears in the labeling. Additionally, the labeling states that elevated levels ascorbic acid, uric acid, total bilirubin, triglycerides, acetaminophen, dopamine, methyl-dopa and levodopa may affect results.

Altitude:

An altitude effect study was performed by testing each of six different venous samples with glucose values from 20-621 mg/dL (Hi and Lo settings disabled) at sea level and at elevated altitudes up to 11,351 feet.

At each altitude tested, results using the SD Check Gold meter were compared to results using the YSI glucose analyzer. At altitudes up to 11,351 feet, results with the SD Check Gold meter were within +/-7.5 mg/dL for results <75 mg/dL and within +/- 15% for results >75 mg/dL.

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 10-40°C and at a relative humidity from 15-90%

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The system accuracy evaluation for the SD Check Gold Blood Glucose Monitoring System has been performed according to EN ISO 15197:2003.

Trained professionals obtained 90 natural samples from the fingertip of study participants. Ten samples were contrived in order to obtain samples <50 mg/dL and >400 mg/dL. Samples ranged in value from 20-600 mg/dL.

Testing was performed with 2 different meters and 1 lot of test strips over a two month period. For comparison, each sample was also tested using the YSI glucose analyzer. The results are summarized below:

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
73% (19/26)	92% (24/26)	100% (26/26)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
39% (68/174)	66% (115/174)	88% (153/174)	98% (171/174)

b. Matrix comparison:

Not applicable. Capillary whole blood is the only indicated sample matrix.

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):

A user study was performed to demonstrate that lay consumers could obtain accurate results using the SD Check Gold blood glucose monitoring system. The study was performed using capillary whole blood from fingertip, palm, forearm, and upper arm sample sites. A total of 171 individuals were recruited for the study. All were in “steady state.” Fingertip sample results ranged in concentration from 72-488 mg/dL.

Using only the labeling intended to be provided with the marketed device and without assistance or coaching, each participant performed their own fingerstick testing on the SD Check Gold BGMS. They were then instructed to perform testing using samples obtained from alternative sites: palm, forearm, and upper arm. Laboratory professionals collected additional capillary blood from each participant for testing on both the SD Check Gold BGMS and the YSI glucose laboratory method.

Of the 171 participants, three individuals were not able to obtain a sample from the upper arm alternative site. One individual was not able to obtain a sample from forearm and upper arm.

The results of the user and alternative site studies are summarized below:

Fingertip Sample Result vs. YSI with Fingertip sample

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
1/3(33%)	3/3(100%)	3/3(100%)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
84/168(50%)	137/168(82%)	160/168(95%)	167/168(99%)

Palm Sample Result vs. YSI with Fingertip sample

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
1/3(33%)	3/3(100%)	3/3(100%)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
97/168(57%)	147/168(88%)	163/168(97%)	168/168(100%)

Forearm Sample Result vs. YSI with Fingertip sample

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
1/3(33%)	3/3(100%)	3/3(100%)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
82/167(49%)	131/167(78%)	161/167(96%)	165/167(99%)

Upper arm Sample Result vs. YSI with Fingertip sample

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
3/3(100%)	3/3(100%)	3/3(100%)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
74/164(45%)	131/164(63%)	153/164(93%)	164/164(100%)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The sponsor included the following expected values for non-diabetic normal glucose levels in their strip labeling:

Time	Range, mg/dL
Fasting and Before Meals *	74 – 106
2 hours after Meals **	Less than 140

* Stedman, TL, Stedman's Medical Dictionary, 27th Edition, 1999.

**American Diabetes Association, Clinical Practice Recommendation Guidelines 2003, Diabetes Care, Volume 26, Supplement1, p.22

N. Instrument Name:

SD Check Gold Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for each additional reading.

2. Software:

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

Yes X or No

3. Specimen Identification:

There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger, palm, forearm, or upper arm only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A calibration code chip is provided with each vial of test strips.

6. Quality Control:

The sponsor is providing a one level of glucose control solution (Level M) with the starter kit for the device. A two level control set (Level M and Level H) is available for purchase, as stated in the labeling. When a test strip is inserted into the meter, a control can be run. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the user manual and customer support for problems.

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

The sponsor performed a readability assessment of the labeling and states that the user manual, strip insert, and control insert are written at 8th grade level or below.

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.