

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

A. 510(k) Number:

k060467

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, electrochemical biosensor, glucose oxidase

E. Applicant:

Diagnostic Devices, Inc.

F. Proprietary and Established Names:

Prodigy Blood Glucose Test System

G. Regulatory Information:

1. Regulation section:

862.1345, Glucose Test System

862.1660, Quality control material, assayed and unassayed

2. Classification:

Class II

Class I

3. Product code:

NBW, Blood glucose test system, 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 Prodigy Blood Glucose Test System is intended to be used for the quantitative measurement of glucose in capillary whole blood from the fingertip and palm. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and not intended for use on neonates. The Prodigy meter is to be used with the Prodigy Blood Glucose Test Strip and the Prodigy Glucose Control Solutions.

3. Special conditions for use statement(s):

For over-the-counter and professional use. It is not intended for the diagnosis of or screening for diabetes mellitus, and not intended for use on neonates. Not to be used in cases of severe dehydration or diabetic ketoacidosis (DKA).

4. Special instrument requirements:

Prodigy Blood Glucose Test System

I. Device Description:

The Prodigy Blood Glucose Test System consists of a meter, two levels of control solution and test strips. The system utilizes an electrochemical method based meter and dry reagent biosensor (test strips) using glucose oxidase for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions. The system also provides voice broadcast function when the meter is used to test.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Achtung TD-4207/ Clever Chek TD-4209/ Clever Chek TD-4222 Glucose test Systems

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

k042005

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Enzyme	Glucose oxidase	Glucose oxidase
Test range	20-600 mg/dL	20-600 mg/dL

Differences		
Item	Device	Predicate
Sample volume	0.7 µL	1.8-2.5 µL
Test time	7 seconds	10 seconds
Temperature and humidity range	10-40 ° C Below 85% RH	10-40 ° C 5-95% RH

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

CLSI EP5-A Evaluation of Precision Performance of Clinical Chemistry Devices

CLSI EP6-P2 Evaluation of the Linearity of Quantitative Analytical Methods

CLSI EP7-A Interference testing in Clinical Chemistry

CLSI EP9-A Method Comparison and Bias Estimation Using Patient Samples

prEN 13640 Stability Testing of *in vitro* Diagnostic Medical Devices

ISO 15197 *In-vitro* Diagnostic Test Systems – Requirements for Blood Glucose Monitoring Systems for Self-Testing

IEC 61010/EN 61010 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use

IEC 60601/EN 60601 Medical Electrical Equipment, General Requirements for Safety

L. Test Principle:

Quantitative measurement of glucose in whole blood with an electrochemical biosensor begins when a drop of blood is introduced on the side of the test strip. The electrons produced from the reaction form a current. Under the potential provided from the meter, a current is generated from the electrons produced during glucose oxidation. The current is calibrated to measure the glucose concentration in the whole-blood sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-day imprecision was evaluated by spiking venous whole blood samples to provide 5 levels of glucose concentration. Each sample was tested ten times using ten different meters (100 measurements for each of the five levels for 500 total measurements). Three different lots of reagent (test strips) were used. Results are summarized below:

	Interval 1 30-50 mg/dL	Interval 2 51-110 mg/dL	Interval 3 111-150 mg/dL	Interval 4 151-250 mg/dL	Interval 5 251-400 mg/dL
Mean	41.8	91.1	143.0	239.6	364.6
SD	2.03	2.76	3.53	6.65	6.48
% CV	4.85	3.03	2.47	2.77	1.78
n	100	100	100	100	100

Day to day imprecision was evaluated by testing 3 levels of control solutions using 10 different meters for 10 days. Each of the 3 control solutions was tested on all 10 meters each day, for 300 total measurements. Three different lots of reagent (test strips) were used. Results are summarized below:

	Low control	Normal control	High control
Mean	83.5	148.1	332.5
SD	3.46	3.81	5.39
% CV	4.15	2.58	1.62
n	100	100	100

b. *Linearity/assay reportable range:*

Spiked recovery was evaluated by preparing spiked glucose samples across the measuring range (20-600 mg/dL). Whole blood was depleted of glucose by allowing it to sit at room temperature. The blood was then spiked to 9 targeted glucose concentrations (20, 40, 60, 90, 120, 200, 320, 420, and 600 mg/dL). Values were

verified using a YSI-2300 glucose analyzer. Each sample was measured 10 times on the Prodigy meter. The mean of each sample was plotted against the YSI-2300 value with a resultant regression equation of $y = 1.00097x + 1.3134$, $r = 0.9978$.

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

Two levels of control material (normal and high) are provided for use with the test system. The controls are prepared gravimetrically in an aqueous matrix. Expected values are verified for each manufactured lot. The open and closed stability were tested.

d. Detection limit:

The reportable range of the assay is 20-600 mg/dL. See linearity study above.

e. Analytical specificity:

The hematocrit effect was evaluated at 20%, 30%, 40%, 50%, and 60% hematocrit levels. Samples in the five different concentrations were measured by using YSI-2300 as a reference method. The results of mean difference analysis showed no significant hematocrit effect from 20% to 60% for samples with glucose concentration levels from 40 to 440 mg/dL. The sponsor defined significant effect as glucose value ± 15 mg/dL at concentrations < 75 mg/dL and glucose value $\pm 20\%$ at concentrations ≥ 75 mg/dL.

Altitude showed no significant effect up to 10,744 feet. The sponsor defined significant effect as glucose value ± 15 mg/dL at concentrations < 75 mg/dL and glucose value $\pm 20\%$ at concentrations ≥ 75 mg/dL.

The sponsor tested the effects of temperature, humidity, and resistance to drop and vibration on the meter's performance. The sponsor claims that there is no effect of these factors on glucose results (defined as within ± 15 mg/dL difference in samples below 75 mg/dL and within $\pm 20\%$ in samples above 75 mg/dL and repeatability of $< 5\%$ CV at all glucose levels before and after each challenge).

The sponsor tested 6 exogenous and 2 endogenous substances for interference with their meter. No interference (defined as $\leq 10\%$) was seen up to the following concentrations:

Acetaminophen – up to 5 mg/dL

Ascorbic acid – up to 2.25 mg/dL

Dopamine – up to 2 mg/dL

L-dopa – up to 3 mg/dL

Methyl dopa – up to 0.5 mg/dL

Tolbutamide – up to 200 mg/dL

Uric acid – up to 10 mg/dL

Triglyceride – up to 2000 mg/dL

The package insert states that no interferences are seen at normal physiological levels of these potential interferents as the levels at which interference is seen are above the normal observed physiological concentrations of these substances.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Healthcare professionals obtained capillary samples from 120 patients at 3 sites (40 per site). The samples ranging in concentration from 31 mg/dL to 470 mg/dL were tested on the Prodigy meter (test method) and the Roche Accu-chek meter (comparator method) and the values were compared. The comparison data is listed in the table below:

Site #	Comparison	N	Slope and y-intercept	R
1	Accu-chek vs. Prodigy	40	$y = 0.963x + 6.2329$	0.9852
2	Accu-chek vs. Prodigy	40	$y = 0.9964x + 3.5113$	0.9897
3	Accu-chek vs. Prodigy	40	$y = 1.0128x + 3.1189$	0.9876

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):*

Lay users (n = 120) were given the instructions for use and asked to fill out a questionnaire related to the readability of the Owner’s Manual and ease of use of the meter. The evaluation results were acceptable. The lay users obtained blood samples from the fingertip using the device and the results were compared to the results obtained on the YSI-2300. The YSI-2300 vs. lay user regression statistics are as follows: $y = 1.036x - 8.087$, $r = 0.969$, for samples ranging in glucose concentration from 29 mg/dL to 441 mg/dL.

In order to assess the accuracy of palm site testing compared to fingertip testing, samples were taken by healthcare professionals from the fingertip and palm of 120 subjects at time of steady state (more than 2 hours since the last meal) and run on the Prodigy meter. The palm vs. fingertip regression statistics on the Prodigy meter are as follows: $y = 0.9912x - 4.4171$, for samples ranging in glucose concentration from 29 mg/dL to 441 mg/dL.

A consumer study was performed to evaluate the use of the Prodigy meter using the palm as an alternative site. The studies were conducted at time of steady state. Sixty lay users read the Owner’s Manual, obtained palm blood samples and performed the blood glucose test on the Prodigy meter. The lay users also obtained fingertip blood samples and performed the blood glucose test on the Prodigy meter. The lay users also filled out a questionnaire related to the ease of obtaining and measuring the sample from the palm. The results of the questionnaire were acceptable. The lay user palm vs. lay user fingertip glucose regression statistics are as follows: $y = 1.0368x - 3.9975$, $r = 0.9847$, for samples ranging in glucose concentration from 45 mg/dL to 401 mg/dL.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The labeling indicates the following expected values:

Time of day	ADA recommendation
Before meals	80 - 120 mg/dL
1 – 2 hours after meals	Less than 180 mg/dL
Bedtime	100 – 140 mg/dL

Source: American Diabetes Association (2005). Standards of Medical Care in Diabetes, Clinical Practice Recommendations 2005, Diabetes Care, 28:S4 – S36.

N. Instrument Name:

Prodigy Blood Glucose Test System

O. System Descriptions:

1. Modes of Operation:

Manual – insertion of test strip and sample application start the test

2. Software: TD 4227 Software

Software language - Assembly 6502, Requires RS232 interface

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

Yes X or No _____

3. Specimen Identification:

Not applicable. Sample is fresh capillary blood from fingertip or palm site. The meter stores up to 450 readings.

4. Specimen Sampling and Handling:

Manual sample (fresh whole blood) acquired by fingerstick or from palm site

5. Calibration:

Calibration information is contained on a coding strip that is contained in each test strip vial. The user codes the meter with the lot code strip and the meter stores the calibration information for strips with that code.

6. Quality Control:

Two levels of quality control are provided with the system

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

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.