

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

A. 510(k) Number:

k053593

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative; electrochemical biosensor

E. Applicant:

Diagnostic Devices, Inc.

F. Proprietary and Established Names:

Prodigy Blood Glucose System

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, Class I

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:
Clinical Chemistry (75)

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. It is intended for use by people with diabetes mellitus at home (Over-the Counter) as an aid in monitoring the effectiveness of diabetes control program. The Prodigy Blood Glucose Test System can also be used at clinical sites by nurses or professional people to test the patient's glucose level in whole blood. 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

4. Special instrument requirements:

Prodigy Blood Glucose Meter

I. Device Description:

The Prodigy Blood Glucose Test System consists of a glucose test meter, test strips, two levels of control solution, and a commercially available (510(k) cleared) lancing device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Taidoc Technology Corporation, Achtung TD-4207, Clever Chek TD-4209 and Clever Chek TD-4222 Glucose Test Systems

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

k042005

3. Comparison with predicate:

The device and the predicate share the same intended use and test principle. Additional similarities and differences are listed below.

Similarities		
Item	Device	Predicate
Brand Name	Prodigy	Achtung TD-4207, Clever Chek TD-4209 and Clever Chek TD-4222 Glucose Test Systems
Intended Use	Intended for home use by diabetics to monitor their blood glucose levels or for use in a clinical setting by healthcare professionals using capillary whole blood.	Same
Detection Method	Amperometry: measuring a current produced by a chemical reaction.	Same
Enzyme	Glucose oxidase	Same
Temperature compensation	Automatic compensation with built in thermister.	Same

Differences		
Item	Device	Predicate
Size (mm)	88x62x22	80x60x20
Weight	26.5	48.79

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

CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

CLSI EP6-P2; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Proposed Guideline

CLSI/NCCLS EP7-P; Interference Testing in Clinical Chemistry; Approved Guideline

EN 60601-1 / 1990 /1998 / 2001; Medical electrical equipment - Part 1: Particular general requirements for the safety

EN 61010-1 / 2001; Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: general requirements

EN 61010-2-101 / 2002 Particular requirements for in vitro diagnostic (IVD) medical equipment

L. Test Principle:

When a whole blood sample is applied to the sample chamber of the test strip, glucose measurement commences. Glucose measurement is based on electrical potential caused by the reaction of glucose with the reagents contained on the strip's electrodes. The glucose in the sample is oxidized by the enzyme glucose oxidase, producing gluconolactone. The current resulting from this enzymatic reaction is measured and converted to glucose concentration by the meter. The magnitude of the current is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Within day imprecision was evaluated by assaying five spiked whole blood samples of differing concentrations in one run using 10 meters and three lots of test strips (n=300). The results are summarized below:

Interval	Results	Lot #1	Lot #2	Lot #3
mg/dL				
30-50	Mean	52.2	50.6	53.1
	SD	2.32	2.54	2.44
	% CV	4.45	5.03	4.59
51-110	Mean	76.5	73.6	77.4
	SD	1.76	1.99	1.66
	% CV	2.30	2.71	2.15
111-150	Mean	113.9	113.9	113.9
	SD	3.40	3.40	3.40
	% CV	2.99	2.99	2.99
151-250	Mean	248.9	241	249.6
	SD	4.47	3.37	6.18
	% CV	1.8	1.4	2.48
251-400	Mean	316.1	311.8	315.3
	SD	5.25	3.9	4.79
	% CV	1.66	1.25	1.52

Day to day imprecision was evaluated by testing three levels of control solutions once a day for 10 days using 10 meters and three lots of test strips (n=300). The results are summarized below (units = mg/dL):

	Low	Normal	High
Control Range mgdL	60-92	109-165	259-389
Mean	75.6	131.8	322.6
SD	1.54	3.38	5.33
% CV	2.04	2.56	1.65

b. *Linearity/assay reportable range:*

The linearity of the glucose measurements was demonstrated by comparing blood samples on the Prodigy glucose meter and the glucose reference method (YSI) across the reportable range of the device (20-600 mg/dL). Whole blood samples were spiked with D-glucose to nine targeted glucose concentrations (20, 40, 60, 90, 120, 200, 320, 420, and 600 mg/dL). For each concentration, ten consecutive tests were performed (5 tests per lot) on each meter. The linear regression of the data yielded the following relationship: $y = 0.998x + 2.989$, $R^2 = 0.999$.

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 mean value for a typical lot is 137 mg/dL (normal) and 347 mg/dL (high). The open, closed, and transport stability were tested. The sponsor's protocol and acceptance criteria were reviewed and found to be acceptable.

d. *Detection limit:*

20 mg/dL – see linearity section above M.1.b

e. *Analytical specificity:*

The sponsor tested the effects of hematocrit (20-60%), temperature, humidity, resistance to drop and vibration and altitude on the meter's performance. The meter was tested at different altitudes to assess the effect of low oxygen levels on the meter performance. No effect on performance was found when three different levels of controls were tested at 10,000 ft. Higher elevations were not tested. The sponsor presented data that supported using the test system between 10°C to 40°C.

The effect of sample hematocrit variation on the Prodigy system was tested by preparing samples of known hematocrit and spiking aliquots of these samples with six different levels of glucose. These samples were assayed on the Prodigy and YSI systems. The results showed less than a $\pm 20\%$ bias at glucose concentrations ≥ 75 mg/dL and less than a ± 15 mg/dL bias at glucose concentrations < 75 mg/dL across the claimed range of 20-60% Hematocrit.

Specificity of the assay was assessed by spiking various endogenous and exogenous compounds into prepared whole blood samples. The sponsor prepared a low whole

blood control (approximately 80 mg/dL) and a high whole blood control (approximately 300 mg/dL) glucose and confirmed these concentrations prior to the addition of the interferents. The sponsor added the interfering substance and assayed each control solution on the Prodigy system. If the change in glucose measurement from the control solution was less than 10%, the sponsor considered this as no interference. The results of the study are presented in the table below:

Interferent	Highest Concentration With < 10% Interference	
	Low Glucose Control (80mg/dL)	High Glucose Control (300mg/dL)
Acetaminophen	5 mg/dL	5 mg/dL
Ascorbic Acid	2.25 mg/dL	3 mg/dL
Dopamine	2 mg/dL	2 mg/dL
L-dopa	3 mg/dL	3 mg/dL
Methyldopa	0.5 mg/dL	0.75 mg/dL
Tolbutamide	200 mg/dL	200 mg/dL
Triglycerides	2000 mg/dL	2000 mg/dL
Uric Acid	10 mg/dL	10 mg/dL

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

One hundred and twenty capillary blood samples were collected and assayed on the Prodigy system and then assayed on the predicate device. The sample range was 27-389 mg/dL. The resulting linear regression is as follows: $y=1.03x -2.98$; $R^2=0.98$.

The accuracy of the assay was evaluated by testing one hundred and thirty five capillary blood samples on the Prodigy system and compared to a reference method (YSI). The sponsor's acceptance criteria were based on ISO 15197 recommendations: 95% of the individual results shall fall within ± 15 mg/dL at glucose concentration <75 mg/dL and within 20% at glucose concentration ≥ 75 mg/dL. The results are presented in the tables below:

Accuracy results for glucose concentration <75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
21/50 (42%)	39/50 (78%)	49/50 (98%)

Accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
102//220 (46%)	165/220 (75%)	205/220 (93%)	215/220 (98%)

A table listing the distribution of the glucose specimens used in this study is presented below:

Number	% samples	Glucose Concentration (mg/dL)
17	12.6	20-50
48	35.6	51-110
36	26.7	111-150
12	8.9	151-250
12	8.9	251-400
10	7.4	400-600

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):

The consumer study was performed at three sites with a total of 120 lay users (17-66 years old, 65% female, with varying education levels). Each participant performed their own fingerstick and tested their blood in duplicate using the instructions in the Prodigy system User's guide. A laboratory professional collected a fingerstick sample and tested the blood in duplicate on the same meter and the reference device (YSI). The results are presented below:

	Number of Samples	Prodigy vs. reference device	r
Lay User Result #1	120	$Y=1.029x-7.204$	0.978
Lay User Result #2	120	$Y=1.023x-5.403$	0.976
Professional Result #1	120	$Y=0.975x+3.740$	0.989
Professional Result #2	120	$Y=0.987x+2.856$	0.989

A table listing the distribution of the glucose specimens used in the study is presented below:

Number	% samples	Glucose Concentration (mg/dL)
12	10	30-50
48	40	51-110
36	30	111-150
12	10	151-250
12	10	251-400

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The package insert indicates the following reference range for fasting blood glucose as recommended by the American Diabetes Association (ADA):

Time Glucose Test Performed	ADA Recommendation
Before Meals	80-120 mg/dL
1-2 hours after meal	<180 mg/dL
Bedtime	100-140 mg/dL

The labeling advises that users should consult their physician to determine their own appropriate range.

American Diabetes Association. Standards of medical care in diabetes. Clinical Practice Recommendations (2005). Diabetes Care, 28 (Supplement): S4-S36.

N. Instrument Name:

Diagnostic Devices, Inc. Prodigy Blood Glucose System

O. System Descriptions:

1. Modes of Operation:

Single use device for the test strips.

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 only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A code strip is supplied with each vial of test strips to calibrate the meter for the vial. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a normal and high glucose solution with this device. After inserting the test strip press the M (memory) key, "CtL" will be displayed and the control mode is activated. This prevents the control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If the control results fall outside these ranges, the user is referred to a list of troubleshooting steps and a customer care number.

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.