

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k062187

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Semi-quantitative, visual interpretation

E. Applicant:

National Diagnostic Products

F. Proprietary and Established Names:

Betachek Blood Glucose (Sugar)

G. Regulatory Information:

1. Regulation section:
21 CFR 862.1345
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Betachek Blood Glucose is a test intended to be used by non-diabetic individuals to estimate their fasting blood glucose (blood sugar) level from a drop of blood obtained from a finger stick.

Any abnormal results should be verified by a medical professional, such as a physician, and confirmed with a quantitative, laboratory reference method. Only a trained medical professional can determine if an individual has diabetes. Test results within the normal range do not necessarily mean that the individual does not have diabetes or pre-diabetes. Any individuals who are concerned that they may have diabetes or pre-diabetes should seek the advice of a physician.

Betachek Blood Glucose is not intended to be used for children or by individuals who are diabetic or pregnant.

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

3. Special conditions for use statement(s):

For over-the-counter use.

This test can not be used to screen or diagnose diabetes.

It should not be used for children or by individuals who are diabetic or pregnant.

This test is only intended for individual use at home.

It is not for use as part of a screening program in a healthcare setting or any other setting.

4. Special instrument requirements:

None

I. Device Description:

The test kit contains two test strips, 2 disposable lancets, 2 alcohol swabs, and a small package of tissues. The test strips are stored in a canister. The color chart for results interpretation is found on the label on the outside of the canister. Each test strip is disposable and may only be used once.

Betachek Blood Glucose Test is a visually read test strip for the semi-quantitative measurement of glucose in fresh capillary whole blood obtained from a finger stick. Each Betachek Glucose test strip contains two reagent zones attached to the end of a plastic strip. The test instructions describe the step-by-step procedure for performing the test. Users are instructed to use the lancets to perform a finger stick. Blood from the finger is applied to a test strip and allowed to react with the chemicals on the strip. The test strip contains two reagent zones, one green and one pink. The color of each zone will vary in intensity depending on the level of glucose in the blood sample. Each container label has a 5-increment color chart for result interpretation ranging from light pink/light green to dark pink/dark green color pairings. Each of the five color pairs corresponds to the following glucose values: 50, 75, 100, 125, and 150 mg/dL. The result on the test strip obtained by the user is compared to the color chart. Users are instructed to find the color match and use the package insert to interpret the test result.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Chemcard

2. Predicate K number(s):

k943503

3. Comparison with predicate

Similarities		
Item	Device	Predicate
Intended use	Detection of abnormal fasting glucose levels	Same
Sample	Capillary whole blood from finger stick	Same

Similarities		
Item	Device	Predicate
Method of interpretation	Visual by color comparison	Same

Differences		
Item	Device	Predicate
Packaging of test, format	Two (2) test strips	One (1) card

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

Method comparison and Bias Estimation using Patient Samples, approved guidelines Clinical and Laboratory Standards Institute (CLSI) EP9-A2.

Interference Testing in Clinical Chemistry; Approved Guideline, Second Edition CLSI EP7-A.

ISO15197:2003 *In vitro* diagnostic tests system- Requirements for self-testing in managing diabetes mellitus

L. Test Principle:

The test uses a drop of capillary whole blood. The glucose in the blood reacts with the glucose oxidase peroxidase, and tetramethylbenzidine dye contained in the test strip. The resulting color development is proportional to the level of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

In order to evaluate reproducibility, three test samples were prepared from lithium-heparinized venous whole blood with glucose concentrations of approximately 54.6, 108, and 132 mg/dL (as measured by a laboratory method). The test samples were randomized and the actual concentration masked from the operators. Four lots of test strips were used. The samples were applied to Betachek Blood Glucose test strips according to the manufacturer's test instructions and each test was interpreted by four different operators. A total of 16 results were obtained for each glucose test sample.

Results were read by comparing the color reaction on the test strip to the color blocks on the label on the device packaging. For the three test samples, observed results were exactly matched or within one color block for all lots and operators.

b. Linearity/assay reportable range:

The color key on the device label consists of color blocks that are assigned values of 50, 75, 100, 125, and 150 mg/dL. This represents the range of glucose values that can be measured with this device.

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

The recommended storage temperature for Betachek Blood Glucose test strips is 39-86 °F. Data from stability studies supported the shelf-life of the device for up to 25 months.

d. Detection limit:

Sensitivity of the test strips was evaluated for each of the five glucose concentrations corresponding to the color blocks of the Betachek GT color chart (50, 75, 100, 125, 150 mg/dL). A total of 21 spiked, lithium heparinized whole blood samples with glucose concentrations ranging from 24 to 151 mg/dL were prepared and tested using a laboratory method (YSI 2300 Stat Plus).

Each sample was then applied to five test strips from three different lots, in random order, for a total of fifteen (15) tests per sample. The concentration of each sample was masked and interpreted by twenty different untrained lay users.

The results for each of the three lots tested were similar and combined in the summary table below. For each glucose sample tested, the percentage of observations at each of the color blocks is indicated. The sponsor defined the sensitivity as where 75% of the test results were positive.

YSI Glucose (mg/dL)	Percent of total observations						
	<50	50	75	100	125	150	>150
23.9 - 25.2	87%	13%	0%	0%	0%	0%	0%
30.5 - 32.2	80%	20%	0%	0%	0%	0%	0%
37.0 - 39.6	87%	13%	0%	0%	0%	0%	0%
42.6 - 44.5	0%	100%	0%	0%	0%	0%	0%
48.6 - 51.3	0%	93%	7%	0%	0%	0%	0%
55.7 - 57.5	0%	87%	13%	0%	0%	0%	0%
62.1 - 64.5	0%	60%	40%	0%	0%	0%	0%
68.2 - 69.7	0%	13%	87%	0%	0%	0%	0%
73.8 - 76.4	0%	0%	93%	7%	0%	0%	0%
81.2 - 82.1	0%	0%	100%	0%	0%	0%	0%
85.6 - 90.1	0%	0%	67%	33%	0%	0%	0%
93.5 - 95.3	0%	0%	27%	73%	0%	0%	0%
99.5 - 104	0%	0%	0%	100%	0%	0%	0%
105 - 108	0%	0%	0%	93%	7%	0%	0%
110 - 113	0%	0%	0%	47%	53%	0%	0%
118 - 120	0%	0%	0%	33%	67%	0%	0%
124 - 128	0%	0%	0%	0%	100%	0%	0%
130 - 133	0%	0%	0%	0%	93%	7%	0%
136 - 139	0%	0%	0%	0%	73%	27%	0%
142 - 145	0%	0%	0%	0%	7%	87%	7%
148 - 151	0%	0%	0%	0%	0%	100%	0%

e. *Analytical specificity:*

The effect of exogenous and endogenous substances on the accuracy of the device was evaluated. The following substances were evaluated: Acetaminophen (1.66 $\mu\text{mol/L}$), Ascorbic Acid (227 $\mu\text{mol/L}$), Dopamine (5.98 $\mu\text{mol/L}$), Gentic acid (117 $\mu\text{mol/L}$), Ibuprofen (2425 $\mu\text{mol/L}$), Levo-Dopa (100 mg/dL), Methyl-Dopa (71.4 $\mu\text{mol/L}$), Salicylic acid (4.37 mmol/L), Tetracycline (34.1 $\mu\text{mol/L}$), Tolazamide (5.0 mg/dL), Tolbutamide (2.37 mmol/L), bilirubin (20 mg/dL), cholesterol (6.8 mmol/L), creatinine (30 mg/dL), triglycerides (2.5 mmol/L), and β -hydroxy-butyric acid (3.0 mmol/L).

Blood samples with normal and elevated triglycerides (2.5 mmol/L) and cholesterol (6.8 mmol/L) were obtained and spiked with glucose at nine

concentrations ranging from 50 to 150 mg/dL. The samples were assayed in duplicate using Betachek test strips.

For all other potential interferants, each substance was added to blood samples containing approximately 75 and 125 mg/dL glucose (test) and compared to the same samples without interferant (control). Eight replicates of both the control and test samples were tested using Betachek test strips.

Results were read by comparing color reaction of the test and control samples to the color blocks on the canister label according to the instructions on the package insert.

For all compounds tested the test sample and matching control sample results were exact matches or within one color block.

Effect of hematocrit on accuracy was evaluated. Samples with glucose concentrations (70, 90, 120, and 140 mg/dL) were prepared to contain 30, 35, 40, 45, 50, 55 and 60% hematocrit. Each test sample was tested n=5 using Betachek test strips. The results for each glucose concentration for each of the varying hematocrit levels were compared to the same samples with normal hematocrit (40-45%). Test samples with 30, 35, 50, 55, and 60% hematocrit were either exact matches or within one color block of the matched samples containing 40-45% hematocrit.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A study was performed to evaluate the accuracy of the Betachek test compared to an established laboratory method (Yellow Springs Instrument). Informed consent was obtained from diabetic and non-diabetic participants who were visiting a health clinic. A total of 132 participants were enrolled and included male and female individuals from 19-86 years old. The study was performed over several days.

Trained laboratory technicians obtained fresh capillary blood specimens from the fingertip for the Betachek testing and lithium heparinized capillary blood for the testing on the laboratory method. In order to span the reportable range of the device, 7 of the 132 specimens were altered, by allowing the glucose to hydrolyze and/or by spiking with glucose. Nine (9) specimens were obtained

from diabetics. Duplicate tests were performed with Betachek test strips by 2 independent operators, using three different lots of test strips. Testing on the laboratory method was performed in duplicate.

Of the 132 participants, sufficient blood was not obtained for testing in duplicate on the laboratory method from three individuals. Sufficient blood for duplicate Betachek testing was not obtained from one individual.

For the evaluable data, the summary of results from 129 participants and 257 Betachek results compared to the laboratory method is found in the table below:

Glucose Conc. by YSI (mg/dL)	N	Betachek GT color block Results (mg/dL)					
		50	75	100	125	150	>150
up to 50	1	2	0	0	0	0	0
51-75	21	6	30	5	0	0	0
76-100	76	0	26	115	11	0	0
101-125	16	0	0	3	21	8	0
126-150	11	0	0	0	0	20	2
>150*	4	0	0	0	0	0	8

*These samples ranged from 152 to 336 mg/dL by the laboratory method.

b. Matrix comparison:

Not applicable. The device is designed for use only with capillary whole blood from finger stick.

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 study was conducted to compare the performance of the Betachek test when used by untrained lay-users versus trained laboratory professionals. A total of 156 male and female participants were enrolled over a two week period and ranged in age from 18-77. Roughly half of the participants were individuals who visited a health clinic in a fasted state for other testing. Other participants were recruited via advertising in a local newspaper. In order to obtain specimens with high glucose levels, approximately 10% were patients visiting a diabetes clinic. All participants were in a fasted state at the time of the test. Informed consent was obtained from all participants.

Participants were provided with an unopened Betachek test kit and asked to perform the test unassisted, following only the instructions provided, and record their results. They were instructed not to disclose their test result. Then a trained laboratory professional performed the Betachek test again and recorded their result. The study was performed with 156 lay consumers, three trained laboratory professionals, and three lots of devices.

The samples tested produced glucose results in the 75-150 mg/dL range. A table demonstrating the agreement in results between lay users and laboratory professionals is shown below. Agreement is defined here as a match in interpretation, Normal (75-100 mg/dL) or Abnormal High (125-150 mg/dL). No Abnormal Low samples were evaluated in this study.

	Betachek color block result	Professional results		
		Abnormal Low 50 mg/dL	Normal 75-100 mg/dL	Abnormal High 125-150 mg/dL
Lay-User Results	Abnormal Low 50 mg/dL	0	0	0
	Normal 75-100 mg/dL	0	110	1
	Abnormal High 125-150 mg/dL	0	3	42
Total		0	113	43
Percent (%) agreement		None tested	97 %	98%

The lay consumers were asked to complete a questionnaire after testing to obtain feedback on the test instructions, such as the level of difficulty performing and interpreting the test. Of the 156 participants, 150 completed the questionnaire. Eighty-six percent (86 %) agreed that the instructions were easy to understand. Ninety-seven percent (97%) agreed that the test was easy to interpret.

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Glucose values obtained by users are only an estimate at the time the test is performed. Results may be interpreted as abnormally low, normal or abnormally high at the time the test is performed.

N. Proposed Labeling:

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.