

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

A. 510(k) Number:

k050224

B. Purpose for Submission:

Request for clearance of new device

C. Measurand:

Blood glucose, home-use glucose monitoring test

D. Type of Test:

Quantitative

E. Applicant:

Neuro Engineering Inc.

F. Proprietary and Established Names:

3test Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR §862.1345, Blood Glucose Test System, Over-the-Counter
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
A glucose test system is intended to measure glucose quantitatively in blood and other bodily fluids. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and pancreatic islet cell tumors.
2. Indication(s) for use:
“The *3test*[®] *Glucose test strip* is intended to measure the glucose in whole blood with the *3test*[®] *Glucose Monitoring System*. It is suitable for a person with diabetes to monitor their blood glucose at home by themselves. The *3test*[®] *Glucose Monitoring System* can also be used at clinical sites by nurses or

professional people to test patient's glucose level in whole blood.

NOTE:

- a. the *3test* is to be used with capillary whole blood from the fingertip
 - b. the *3test* is not for use with neonates
 - c. the *3test* meter is to be used with the 3test Blood Glucose Test Strip, and the *3test* High and Low Glucose Control Solutions “
3. Special conditions for use statement(s):
This product is intended for over-the-counter and point-of-care use.
 4. Special instrument requirements:
None; this is a complete blood glucose monitoring system.

I. Device Description:

The *3test*[®] Glucose Monitoring System consists of a hand-held blood glucose meter, test strips, and two levels of control materials. Each lot of test strips has a code chip containing lot-specific calibration information that the machine reads automatically. The meter is turned on by strip insertion; the user then supplies finger-tip blood or control solution to the strip and the meter makes an audible tone and starts the assay, which completes in ten seconds. The meter's software converts the results read off the test strip into a plasma glucose concentration and displays the value on the meter's LCD screen. Each test strip contains three different reaction areas: after the test is complete, the user breaks off the used reaction area with a provided tool and stores the strip for subsequent tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Bayer Glucometer Elite Blood Glucose Meter and Test Strips
2. Predicate 510(k) number(s):
k964630 (the Elite series has been subject to multiple 510(k) submissions since the claimed predicate including k043158, k020208, k990649, and k991242)
3. Comparison with predicate:

Similarities		
Item	3test	Ascensia ELITE
Intended Use	Blood glucose monitoring for home and point-of-care	Same
System Components	Meter, calibration code strip, test strip, check strip, battery, control solutions	Same
Specimen	Capillary blood	Same, and approved for arterial and neonatal specimens
Test Principle/ Enzyme/ Mediator	Electrochemical/ Glucose oxidase/ Potassium ferricyanide	Same/ same/ same
Test Range	20 – 600 mg/dL	20 – 600 mg/dL
Hematocrit Range	30 – 55%	20 – 60%
Calibration	Automatic (code strip)	Same
Stability	Closed strips and controls: 20 months Opened strips and controls: 3 months	Same
Sample Volume	2.0 ul	2.0 ul
Power Source	Two 3V lithium batteries	One 3V lithium battery
Differences		
Item	3test	Ascensia ELITE
Test Time	5 seconds	30 seconds
Operating Range	57 – 104° F, relative humidity 20 - 90%,	50 – 104° F, relative humidity 20 - 80%
Memory Capability	100 test results	20 test results
Size	100x58x21 (mm)	81x51x14 (mm)
Weight	57 grams	50 grams

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

Area of Study	Reference Procedure	Procedure Title
Method Comparison/ Anticoagulant Studies	NCCLS EP9-T	Method Comparisons and Bias Estimations Using Patient Samples.
Precision	NCCLS EP5-T2	User Evaluation of Precision Performance of Clinical Chemistry Devices
Linearity	NCCLS EP6-P	Evaluation of the Linearity of Quantitative Methods
Interferences/ Cross-Reactivity	NCCLS EP7-P	Interference Testing in Clinical Chemistry
Guidance	CDRH Guidance	CDRH Review Criteria Portable Glucose Monitoring Devices Intended for Bedside Use in the Neonatal Nursery
	NCCLS Guideline C30-A	Ancillary (bedside) blood glucose testing in acute and chronic care facilities.

L. Test Principle:

The test is based on the release of electrical potential after a two-step reaction where glucose and ferricyanide, in the presence of glucose oxidase, are converted into gluconolactone and ferrocyanide. Ferrocyanide, when electrical current is applied, becomes ferricyanide and releases electrons; the increase in current measured after 10 seconds by the meter is proportional to the glucose concentration. As the rate of the chemical reaction is proportional to temperature, the meter also takes the temperature into account when calculating the glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision was determined at three POC (point-of-care) and three POL (physician office laboratories) by health-care professionals. Five levels of glucose-spiked blood (hydrolyzed overnight) were tested twenty times at each site, covering a range between 40 mg/dL and 400 mg/dL. Within-day precision results are shown in the table below:

3test Blood Glucose Monitoring System: Within-day Precision

Point of Care Studies						
Site 1	YSI (mg/dL)	41	75	127	203	311
	3test Mean ± SD	41 ± 2.4	77.1 ± 4.1	125 ± 7.0	206 ± 6.7	314 ± 11.7
	%CV	5.9	5.4	5.6	3.3	3.7
Site 2	YSI (mg/dL)	48	98	142	221	372
	3test Mean ± SD	50 ± 2.7	100 ± 5.1	153 ± 6.5	220 ± 12.1	369 ± 11.8
	%CV	5.4	5.1	4.3	5.5	3.2
Site 3	YSI (mg/dL)	45	91	135	186	294
	3test Mean ± SD	46 ± 3.0	96 ± 5.5	142 ± 7.8	194 ± 10.3	305 ± 13.6
	%CV	6.5	5.7	5.5	5.3	4.5
Physician Office Laboratories						
Site 1	YSI (mg/dL)	47	82	142	196	309
	3test Mean ± SD	47 ± 2.7	82 ± 4.6	142 ± 5.3	199 ± 8.0	312 ± 12.1
	%CV	5.7	5.6	3.7	4.0	3.9
Site 2	YSI (mg/dL)	50	104	127	213	262
	3test Mean ± SD	51 ± 2.4	106 ± 5.8	130 ± 6.2	216 ± 11.6	272 ± 10.8
	%CV	4.7	5.5	4.7	5.4	4.0
Site 3	YSI (mg/dL)	43	75	147	226	325
	3test Mean ± SD	45 ± 2.6	77 ± 4.6	151 ± 6.7	230 ± 10.8	333 ± 11.6
	%CV	5.8	6.0	4.5	4.7	3.5

Between-day precision was tested at three POC sites and three POL sites by health-care professionals. Five levels of glucose-spiked blood (hydrolyzed overnight) were tested 10 times per day for five days at each site, covering a range between 50 mg/dL and 400 mg/dL. Precision was similar at both kinds of sites, so only POC results are summarized below:

3test Blood Glucose Monitoring System: Between-day Precision at 3 POC Sites

		Glucose Concentration by YSI (mg/dL)				
		50	110	150	250	400
Site 1	Mean 3test (mg/dL)	52.6	115.3	154.3	254.3	408.7
	% CV	5.7	5.4	3.9	3.3	2.9
Site 2	Mean 3test (mg/dL)	55.0	110.5	152.5	252.3	412.2
	% CV	5.5	4.9	4.3	3.7	2.6
Site 3	Mean 3test (mg/dL)	52.6	114.5	156.0	252.5	406
	% CV	6.6	5.8	3.4	3.5	3.0

The sponsor measured the difference in blood glucose values between the three reaction chambers on each strip by using blood samples of known value across the measurement range. Readings were collected for each reaction chamber on 15 strips and averaged by reaction chamber. Mean values between the three chambers varied 2.5% - 4.0%. This met the sponsor's acceptance criterion of $\leq 5\%$ difference.

b. Linearity/assay reportable range:

Heparinized venous whole blood was allowed to glycolyze for 24 hours before testing then aliquoted and spiked with glucose. Twenty concentrations spanning 20 ~ 600 mg/dL were tested 8 times each by 3test (one lot of strips) and YSI and the mean value of each aliquot was calculated. The regression analysis showed a linear relationship between the 3test and the YSI method: $y = 1.005x + 0.851$, $R = 0.999$.

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

Control solutions are prepared by gravimetrically adding glucose to the control base solution. Value assignments for each lot of control are determined using 20 replicates of one test strip lot read on a 3test meter over 10 days to determine mean, standard deviation, and %CV.

Real-time shelf life studies performed by the manufacturer indicate that unopened test strips have a 20 month life-span. Once the strip container is opened, the test strip has been shown to be stable for 3 months.

d. Detection limit:

The low and high detection limits for the 3test system have been set at 20 and 600 mg/dL glucose. Readings below or above these values will generate a "LO" or "HI" result respectively.

e. Analytical specificity:

Assay interferences were tested in a dose-response manner following NCCLS EP7-A guidelines. Aliquots of the blood were supplemented with glucose to a final concentration of 100 mg/dL and measured on an YSI analyzer. The interferent was prepared with an appropriate solvent, and spiked into the 100 mg/dL blood. A control pool was prepared by supplementing the blood with solvent minus the interferent. A series of four to five levels that included the maximum concentration of the substance that would be expected to be encountered in clinical practice were used for each interferent.

The table below shows the effect of common interferences at the upper end of normal or therapeutic levels on 3test test levels:

**Interference at High-Normal or High Therapeutic Levels
3test System**

Interferent	Upper End Therapeutic or Normal Range	Highest Concentration Tested with No Interference	Interferent	Upper End Therapeutic or Normal Range	Highest Concentration Tested with No Interference
Acetaminophen	2 mg/dL	8 mg/dL	Tolazamide	3 mg/dL	100 mg/dL
Ascorbic Acid	2 mg/dL	3 mg/dL	Tolbutamide	10 mg/dL	100 mg/dL
Bilirubin	1.2 mg/dL	20 mg/dL	Triglycerides	190 mg/dL	3000 mg/dL
Cholesterol	300 mg/dL	500 mg/dL	Uric Acid	7.7 mg/dL	20 mg/dL
Creatinine	1.5 mg/dL	30 mg/dL	Citrate (K+)	500 mg/dL	1000 mg/dL
Dopamine	N/A	13 mg/dL	EDTA (K+)	150 mg/dL	300 mg/dL
Ibuprofen	4.2 mg/dL	40 mg/dL	Fluoride	500 mg/dL	1000 mg/dL
Methyl-Dopa	0.75 mg/dL	2.5 mg/dL	Heparin	4000 U/dL	8000 U/dL
Salicylates	30 mg/dL	50 mg/dL	Oxalate (K+)	400 mg/dL	800 mg/dL
Tetracycline	0.4 mg/dL	4 mg/dL	Thymol	140 mg/dL	Interfered at 140 mg/dL

The meter was tested at different altitudes to assess the effect of low oxygen levels on meter performance. No effect on performance was found when three different levels of blood were tested up to 8800 ft. Higher elevations were not tested. The sponsor presented data that supported using the test system between 14°C to 40°C.

Hematocrit Effect:

The effect of sample hemoglobin variation on the 3test system was tested experimentally by preparing samples of known hematocrit (Hct) and spiking aliquots of these samples with three different levels of glucose. These samples were run on the 3test and YSI; there was less than an $\pm 11\%$ bias across the claimed range of 30 ~ 55% Hct.

f. *Assay cut-off:*
Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

See clinical studies section below.

b. *Matrix comparison:*

Not applicable. This device is indicated for use with capillary blood only. The meter's software adjusts the whole-blood glucose reading to a plasma-equivalent reading.

3. Clinical studies:

Two separate clinical studies of the 3test system performance were performed. Results are presented in the Clinical Sensitivity section below.

The consumer study was performed at three POC sites with a total of 150 lay-users. The lay-users ranged in age, education, and were about equally divided between males and females; type-2 diabetes was more common in the participant groups, although not all participants have diabetes. The native language of most of the participants was English. Each participant performed their own fingerstick and tested their blood using the instructions in the User's Guide. A trained technician then performed another fingerstick and tested the blood on the same meter. Capillary blood was collected and measured on a YSI analyzer.

Another study was performed by two health care professionals (HCP) at three POC and three POL sites (n = 6 HCP). Forty patient volunteers participated at each site; six fingersticks were performed for testing on the 3test and six capillary tubes of blood were collected for testing on the YSI analyzer.

a. *Clinical Sensitivity:*

Consumer Study Results : 3test vs. YSI

Site		3test v. YSI	r value	Sample Range (mg/dL, by YSI)	% Parkes Error Grid	
					A	B
Consumer Results						
1	n = 47	$y = 1.001x + 0.558$	0.987	66 – 250		
2	n = 55	$y = 1.042x - 2.777$	0.987	64 – 340		
3	n = 48	$y = 0.999x - 0.388$	0.981	65 – 351		
Sum	n = 150	$y = 1.021x - 2.000$	0.984	64 – 351	98.7%	1.3%
Technician Results						
1	n = 47	$y = 0.995x + 0.398$	0.982			
2	n = 55	$y = 1.012x + 3.851$	0.986			
3	n = 48	$y = 0.971x + 4.483$	0.985			
Sum	n = 150	$y = 1.004x + 2.119$	0.984		98%	2 %

HCP Study Results: 3test vs. YSI

Site (n = 40)	3test v. YSI	r value	Sample Range (mg/dL, by YSI)	% ± 20% Reference value	% Parkes Error Grid	
					A	B
POC 1	$y = 1.033x - 0.32$	0.994	65.7 – 344.7	97.5%	97.5	2.5
POC 2	$y = 1.028 - 1.45$	0.989	63.7 – 327.2	100	97.5	2.5
POC 3	$y = 1.064 - 5.06$	0.984	55.8 – 348.2	100	97.5	2.5
POL 1	$y = 1.025x - 2.08$	0.989	64.2 – 323	100	100	0
POL 2	$y = 1.006x + 2.58$	0.989	64.8 – 346	100	97.5	2.5
POL 3	$y = 1.043 - 2.70$	0.992	61 - 326	100	97.5	2.5

- b. *Clinical specificity:*
Not applicable.
 - c. Other clinical supportive data (when a. and b. are not applicable):
4. Clinical cut-off:
Not applicable.
 5. Expected values/Reference range:
The normal fasting adult glucose range for a non-diabetic is 70 – 105 mg/dL. One to two hours after a meal, normal blood glucose levels should be less than 140 mg/dL. A medical professional should determine the range that is appropriate for diabetes patients.

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.