

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

A. 510(k) Number:

k092688

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative amperometric whole blood glucose dehydrogenase (GDH-FAD)

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

FORA POCT S10 Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Blood Glucose Test System
2. Classification:
Class II
3. Product codes:
LFR, Glucose Dehydrogenase, Glucose
4. Panel:
75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
Refer to indications for use below.
2. Indication(s) for use:
The FORA POCT S10 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose with fresh capillary whole blood from the finger and venous whole blood samples. It is indicated for multiple patients use by health care professionals in health care facilities as an aid in monitoring the effectiveness of diabetes

control program. The system is only used with single-use lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus. It is not intended for use on neonates.

The FORA POCT S10 Blood Glucose test strips are for the quantitative measurement of glucose with fresh capillary whole blood from the finger and venous whole blood samples. The FORA POCT S10 test strips are for use only with the FORA POCT S10 Blood Glucose meter.

3. Special conditions for use statement(s):
 - Not intended for diagnosis or screening of diabetes mellitus
 - Not intended for use on neonates
 - Not for use on critically ill patients, dehydrated patients, patients in shock, or hyperosmolar patients
 - Not for alternative site testing
 - For in vitro diagnostic use only
 - For multiple patient use with single-use lancing devices
 - For prescription use
4. Special instrument requirements:
FORA POCT S10 Blood Glucose meter

I. Device Description:

The FORA POCT S10 Blood Glucose Monitoring System consists of: FORA POCT S10 Blood Glucose meter with docking station, FORA POCT S10 test strips, and one bottle of control solution (Level 2), mini USB cable, AC/DC power adapter, carrying case and operator's manual. The meter contains a built-in barcode scanner. Operator, specimen, and test strip identification may be scanned or manually entered via the keypad. Additional control solutions (Levels 1 and 3) may be purchased separately. Operators are instructed to only use auto-disabling, single use lancing devices, sold separately.

The FORA POCT Management System, data management software, is available separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
TaiDoc Pro I Glucose Test Strips for use with Clever Chek TD-4222, Clever Chek TD-4230, Clever Chek TD-4231 Blood Glucose Meters and Clever Chek TD-3250C, and Fora Comfort 2 in 1 TD-3260 Blood Glucose plus Blood Pressure Monitors
2. Predicate 510(k) number(s):
k082169

3. Comparison with predicate:

Similarities and Differences Test System		
Item	Predicate - k082169	New Device
Indications for use	Intended for use in the quantitative measurement of glucose with fresh capillary whole blood from the finger and venous whole blood samples, as an aid in monitoring the effectiveness of diabetes control program	Same
Measurement range	20 to 600 mg/dL	Same
Test principle	Amperometric	Same
Enzyme/assay	Glucose dehydrogenase-flavin adenine dinucleotide (FAD)	Same
Sample type	Capillary and venous whole blood	Same
Alternative site use	Palm, forearm, upper arm, calf and thigh	None-fingertip samples only
Prescription or OTC use and setting	Prescription and OTC use; in clinical settings and for home use	Prescription use only; for use on multiple patients

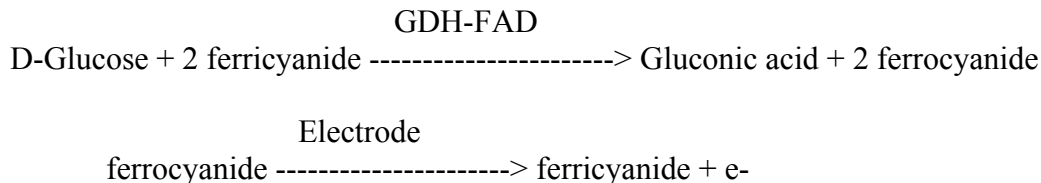
K. Standard/Guidance Document Referenced (if applicable):

- CLSI EP-5A2: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline
- CLSI EP-9A: Method comparison and bias estimation using patient samples; Approved guideline
- CLSI EP7-A2: Interference testing in clinical chemistry, Approved guideline.
- ISO 15197, In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus, 2003
- ISO 14971: Medical devices – Application of risk management to medical devices

L. Test Principle:

The test strips used in this device employ electrochemical biosensor technology and feature an electrode containing the glucose dehydrogenase in the presence of the coenzyme Flavin Adenine Dinucleotide (FAD). The chemical reaction utilizes GDH-FAD to catalyze the formation of gluconic acid from the oxidation of glucose whereby two electrons are produced. Through the mechanism of the mediator, electrical current is generated and it is proportional to the quantity of glucose in the sample.

The reaction principle of reagent depends on following reaction equation.



M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Repeatability testing was performed using fresh venous whole blood obtained from several non-diabetic volunteers. The whole blood was spiked or allowed to glycolyze in order to obtain 5 glucose concentrations ranging from 46.1 – 330.8 mg/dL. The hematocrit range was 38%-54%. Testing consisted of 10 measurements of each glucose sample using 10 meters for a total of 100 measurements per sample. The results are summarized below:

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
46.1	1.35	2.93
103.2	2.80	2.71
145.8	2.58	1.77
207.6	3.87	1.86
330.8	8.34	2.52

The Day to Day precision testing was performed using five glucose levels of control solutions (A-E in the table) using ten meters over a period of 10 days, for a total of 100 measurements per level. The study was performed with three lots of test strips.

Lot 1					
Control	A	B	C	D	E
Mean (mg/dL)	43.3	80.3	220.4	387.6	567.7
SD	1.4	1.66	4.01	9.6	14.0
CV (%)	3.2	2.07	1.82	2.47	2.48
Lot 2					
Control	A	B	C	D	E
Mean (mg/dL)	44.6	79.5	218.1	382	566.9
SD	1.5	1.8	3.88	8.0	14.8

CV (%)	3.4	2.28	1.78	2.09	2.6
Lot 3					
Control	A	B	C	D	E
Mean (mg/dL)	45.6	78.8	218.3	385.1	571.5
SD	1.6	1.66	4.53	6.6	14.4
CV (%)	3.5	2.11	2.08	1.7	2.52

Repeatability and between-day studies were also performed at three (3) Point of Care sites by nine (9) operators reflective of the intended users of the device. All operators attended a training session on the use of the test system prior to performing any testing. TaiDoc intends to provide this training with the marketed device.

Between-day testing was performed by assaying five levels of control material using 3 lots of test strips and 10 different meters over ten days, at 3 sites. In total each control was tested n=900

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
41.1	1.79	4.4
121.6	4.13	3.4
334.9	10.58	3.2
409.4	13.57	3.3
597.5	15.53	2.6

Repeatability testing was performed by assaying venous whole blood EDTA samples, spiked with six levels of glucose. Each sample was evaluated with 3 lots of test strips and 10 different meters at 3 sites within one day. In total each sample was tested n=300 per site.

Site 1

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
41.7	1.39	3.3
81.7	2.07	2.5
131.0	4.54	3.5
210.3	7.06	3.4
312.6	9.44	3.0
599.6	14.42	2.4

Site 2

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
41.4	1.22	2.9
81.3	2.17	2.7
131.9	4.64	3.5
215.2	7.05	3.3
311.5	9.6	3.1
598.8	14.19	2.4

Site 3

Glucose Conc. (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40.7	1.29	3.2
81.1	2.19	2.7
131.7	4.58	3.5
214.6	6.88	3.2
308.7	9.44	3.1
598.3	15.37	2.6

b. Linearity/assay reportable range:

A linearity study was conducted using venous whole blood incubated for 16 hours at room temperature to deplete glucose in the sample. Glucose was adjusted to 11 concentration levels ranging from 11-773 mg/dL. Five measurements were performed at each glucose concentration with one lot of test strips on the FORA POCT S10 test system. For the study, the upper and lower flags for less than 20 mg/dL and greater than 600 mg/dL were disabled. All samples were also tested on the YSI 2300 analyzer to generate the expected values. The observed values were plotted against the expected values and an appropriate line fitted by standard linear regression analysis.

The analysis yielded this result: $y = 1.0071x - 1.7997$, $r^2 = 0.999$.

The results of the study support the sponsor's claim that the test system is linear from 20-600 mg/dL.

Results below 20 mg/dL and results greater than 600 mg/dL are flagged by the test system and reported only as "Less than 20 mg/dL" or "More than 600 mg/dL."

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

The unopened vials of test strips are stable for 24 months when stored at 2 - 32°C. Once opened, they are stable for 90 days when stored at 2 - 32 °C.

The FORA Control Solutions were cleared under k093724. Value assignment was validated with 25 FORA POCT S10 glucose meters, one lot of test strips, and 25 measurements per level. Test results must fall within the range printed on the test strip vial.

Control Solutions are stable for twenty-four (24) months from the date of manufacture when stored at 36°-86°F (2°-30°C) unopened. Each bottle of control is stable for three months (90 days) after opening, if tightly closed after each use and within the labeled expiration date of the product.

d. Detection limit:

The detection limit is 20 mg/dL. See linearity/assay reportable range above.

e. Analytical specificity:

Interference testing was conducted to determine the effect of selected endogenous and exogenous substances on the test system. The potential interferants were tested at therapeutic or normal ranges and also at above therapeutic and toxic ranges. Venous blood samples at two glucose concentrations, 60-70 mg/dL and 150-160 mg/dL, were prepared and divided into a test (dosed) pool and a control pool. Paired differences of glucose measurements between test samples and control samples were calculated to determine the bias. There was less than +/-10% bias for the substances listed below at the listed concentrations.

Substance	Concentration (mg/dL)
Acetaminophen	10
Acetylsalicylic acid	50
Acyclovir	3.1
Allopurinol	5
Amitriptyline	0.25
Amoxicillin	11
Ampicillin	5
Ascorbic Acid	4
Atenolol	10
Bicarbonate	40 mM
Bile Acids	6
Bilirubin (unconjugated)	20
Caffeine	10
Calcium	5 mM
Chloride	140 mM
Cholesterol	500
Clonidine	2
Creatinine	5
Digoxin	0.16

Diphenhydramine	1
Dopamine	0.1
EDTA	702
Enalapril	0.15
Erythromycin	20
Estrone	0.1
Famotidine	0.13
Fluoxetine	0.8
Fructose	1000
Furosemide	2
Galactose	1000
Gentisic Acid	2
Glyburide	1.07
Hemoglobin	500
Ibuprofen	55
Lactose	1000
Lidocaine	6
L-Dopa	0.7
Magnesium	5 mM
Mannitol	5000
Mannose	125
Maltose	1000
Metaproterenol	1.81
Methyl-Dopa	1.25
Metoprolol	0.3
Naproxen	100
Nifedipine	0.17
Nortriptyline	0.15
Penicillin	12
pH value	6.7-9.8
Phenytoin	10
Piroxicam	5
Potassium	10 mM
Pralidoxime Iodide	1.25
Salicylic acid (aspirin)	60
Sodium	200 mM
Sorbitol	1000
Sulfamethoxazole	120
Sulfate	5 mM
Terfenadine	0.45
Tetracycline	4
Theophylline	25
Tolazimide	12.5
Tolbutamide	64
Total Protein	12,000

Triglycerides	2000
Urea	600
Uric Acid	10
Vancomycin	25
Verapamil	0.45
Vitamin E	20
Warfarin	2
Xylose	3

The test strip labeling contains the following warnings for these compounds:

Mannitol: Falsely elevated blood glucose levels may be seen with high blood concentrations of mannitol >5,000 mg/dL as may occur with high dose mannitol administration, obesity (when dosed on a per kilogram basis), and or delayed renal clearance. Test results should be confirmed with a laboratory method for patients that fit any of these clinical situations or if results do not correlate with clinical symptoms.

Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood will give falsely elevated blood glucose results.

Pralidoxime containing compounds:

Do not use this test system with any patients being treated with pralidoxime containing compounds.

Mannose: Large quantities of food and dietary supplements containing mannose in high doses may interfere with this test.

Acetaminophen (>10 mg/dL), dopamine (>1.25 mg/dL), methyl-dopa (>1.25 mg/dL) and L-dopa (>0.7 mg/dL) at concentrations in excess of therapeutic levels may produce falsely elevated glucose results. Uric acid at physiological concentrations > 10 mg/dL may produce falsely elevated glucose results.

Hematocrit:

The effect of different hematocrit levels was evaluated using blood samples at nine glucose concentrations spanning the range of the device (20-600 mg/dL). The glucose samples were prepared from whole blood at twelve 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. The data supports the sponsor's claim that hematocrit 20%-60% does not significantly interfere (more than $\pm 15\%$) with glucose measurements using the test system.

- f. Assay cut-off:
Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

The sponsor performed combined accuracy and point-of-care studies and according to the requirements of ISO 15197. Testing was conducted at 3 sites with seven (7) operators reflective of the intended users of the device. Fresh capillary blood samples from the finger-tip were obtained from a total of 300 subjects, 100 subjects at each site, and tested on both the FORA POCT S10 BGMS test system and a reference method, Yellow Springs Instrument (YSI-2300). Additionally, a venous whole blood sample was obtained from the same subjects and tested on each method.

Glucose samples spanned the reportable range of the device. Of the 100 specimens at each site, 5 specimens >400 mg/dL were spiked (15 total) and 7 specimens in total were allowed to glycolyze to obtain a low glucose value <40 mg/dL. The results are summarized below:

Capillary blood from finger-tip

Site 1 Results

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
44% (7/16)	94% (15/16)	100% (16/16)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
58% (49/84)	95% (80/84)	99% (83/84)	100% (84/84)

Site 2 Results

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
67% (10/15)	100% (15/15)	100% (15/15)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
55% (47/85)	87% (74/85)	99% (84/85)	100% (85/85)

Site 3 Results

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
82% (14/17)	100% (17/17)	100% (17/17)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
87% (72/83)	99% (82/83)	100% (83/83)	100% (83/83)

Linear Regression Analysis

Site 1 $y = 0.9792x - 0.8898$ ($r^2 = 0.9918$)
 Site 2 $y = 0.988x + 1.0676$ ($r^2 = 0.9861$)
 Site 3 $y = 1.008x - 1.252$ ($r^2 = 0.993$)

Venous EDTA whole blood

Site 1 Results

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
44% (7/16)	94% (15/16)	100% (16/16)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
60% (50/84)	95% (80/84)	99% (83/84)	100% (84/84)

Site 2 Results

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
67% (10/15)	100% (15/15)	100% (15/15)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
54% (46/85)	86% (73/85)	99% (84/85)	100% (85/85)

Site 3 Results

For glucose concentrations ≤ 75 mg/dL

within ± 5 mg/dL	Within ± 10 mg/dL	within ± 15 mg/dL
94% (17/18)	100% (18/18)	100% (18/18)

For glucose concentrations > 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
83% (68/82)	93% (76/82)	99% (81/82)	100% (82/82)

Linear Regression Analysis

Site 1 $y = 0.9792x - 0.8898$ ($r^2 = 0.9918$)

Site 2 $y = 0.988x - 1.0676$ ($r^2 = 0.9861$)

Site 3 $y = 0.945x + 8.62$ ($r^2 = 0.990$)

b. Matrix comparison:

The test system may be used with capillary whole blood from the finger-tip and venous EDTA whole blood specimens.

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):

Not applicable

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Expected blood glucose values for people without diabetes were cited from literature¹ and presented in the labeling as follows:

Fasting: less than 100 mg/dL,

2 hours after meal: less than 140 mg/dL

¹American Diabetes Association (2010) Clinical Practice Recommendations. Diabetes Care, 33, (Supplement 1): S1-100.

N. Instrument Name:

FORA POCT S10 Blood Glucose Meter

O. System Descriptions:

1. Modes of Operation:

Each test strip is single use and requires a sample volume of 0.7 μ L blood.

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes X or No

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No X_____

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:

Patient identification may be scanned with the barcode reader or manually entered.

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger and venous whole blood. Samples are applied directly to the test strip.

5. Calibration:

Operators are required to code the meter when using the system for the first time or when using a using new vial of test strips. This is accomplished by scanning the test strip vial barcode with the barcode reader.

6. Quality Control:

One level of control solution (Level 2) is supplied with the device. Additional control solutions (Levels 1 and 3) may be purchased separately. Recommendations on when to test the control materials are provided in the labeling. The labeling also states that users should follow local, state, and federal regulations for quality control testing.

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

1. An altitude effect study was performed by testing nine different venous samples with glucose values from 40-658 mg/dL (upper meter limit disabled) using the FORA POCT S10 Blood Glucose Monitoring System in an altitude simulation chamber. Testing was performed at sea level, 5,000, 11,500, and 15,000 feet using four meters.

At each simulated altitude tested, results using the FORA POCT S10 test system were compared to results using the YSI glucose analyzer.

At altitudes up to 15,000 feet, overall results were within +/-10% of YSI values.

2. Temperature and humidity operating conditions were evaluated for temperatures ranging from 10°C to 40°C and relative humidity from 10% to 85%. Protocol and acceptance criteria were provided and found to be acceptable. The results supported the Sponsor's claimed operating temperature from 10°C to 40°C (50°F to 104°F) and relative humidity below 85%.

3. EMC testing was evaluated and certified by an external company and a letter of attestation was issued to TaiDoc on April 2, 2009.
4. The device is intended for multiple patient use by health care professionals. Micro-Kill+ cleaner disinfectant towels (EPA registration # 59894-10-37549) were validated for use with the meter whereby complete inactivation of live virus was demonstrated. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter after 10,000 cleaning and disinfection cycles designed to simulate 3 years of device use. Labeling has been reviewed for adequate instructions on the validated cleaning and disinfection procedures. The sponsor does not market a lancing device for use with the device. Auto-disabling, single use lancing devices need to be purchased separately.

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.