May 23, 2022

Arkray, Inc.
Dhwani Thakkar
Regulatory Affairs Project Manager
5182 West 76th Street
Minneapolis, MN 55439

Re: K200788
Trade/Device Name: Assure® Titanium Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: PZI
Dated: June 14, 2021
Received: June 15, 2021

Dear Dhwani Thakkar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie Kelm, Ph.D.
Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200788

Device Name
Assure® Titanium Blood Glucose Monitoring System

Indications for Use *(Describe)*

• The Assure Titanium Blood Glucose Monitoring System consists of the Assure Titanium Blood Glucose meter and the Assure Titanium Blood Glucose test strips. The Assure Titanium Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for in vitro diagnostic, point of care use in endocrinology clinics and nursing or skilled nursing facilities, for multiple patient use. This system should only be used with single use, auto-disabling lancing devices for drawing finger stick capillary blood.
• The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.
• The system is not intended for use in acute care or hospital settings.
• The system is not intended for neonatal use.
• The system is for prescription use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. Administrative Information

Applicant's Name and Address	Yoshiharu Uehata ARKRAY, Inc. Yousuien-nai, 59 Gansuin-cho Kamigyo-ku, Kyoto 602-0008 Japan Establishment Registration # 3003422726
Primary Contact	Dhwani Thakkar Regulatory Affairs Project Manager ThakkarD@arkrayusa.com
Secondary Contact	Daya Ranamukhaarachchi, PhD V.P. Regulatory and Scientific Affairs RanamukD@arkrayusa.com
Phone	408-234-0804
Fax	1-855-924-2725
Email	RanamukD@arkrayusa.com
Date Prepared	June 14, 2021

2. Device Information

Device

Trade Name	Assure® Titanium Blood Glucose Monitoring System
510(k) Number	K200788
Classification Name	Prescription Use Blood Glucose Meter for Near-Patient Testing
Common Name	Glucose Test System
Product Code	PZI
Classification Panel	75 – Clinical Chemistry
Device Classification	21 CFR § 862.1345

3. Predicate Device Information

Predicate Device Name	Predicate Device 510(k) Number
StatStrip Glucose Hospital Meter System	K132121

4. Device Description

The Assure Titanium Blood Glucose Monitoring System consists of a battery-powered meter, disposable test strips Assure Titanium Blood Glucose Test Strips, and control solutions. The Assure Titanium Blood Glucose Test Strips utilizes biosensor technology for the quantitative determination of glucose concentrations in capillary blood samples. Glucose in the blood reacts with the reagent in the test strip, and this produces a small electric current (amperometry). The strength of this current is proportional to the concentration of glucose in the blood. The meter measures this current and calculates the patient's glucose level.

Test principle:

The sample (whole blood) is drawn by capillary action at the tip of the test strip. As depicted in the chemical reactions listed below in **Figure 1**, glucose in the sample reacts with glucose oxidase (GOD) and Hexaammineruthenium (III) chloride in the test strip. This produces Hexaammineruthenium (II) chloride. Hexaammineruthenium (II) chloride is produced in proportion to the glucose concentration of the blood sample. Oxidation of the Hexaammineruthenium (II) chloride produces an electric current. The meter converts the current to the glucose concentration and displays it as the test result.

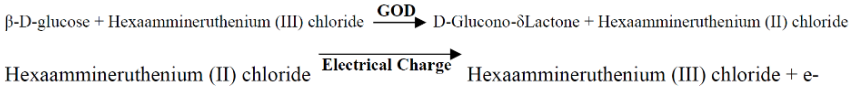

Figure 1: Principle of Action for Assure Titanium Blood Glucose Monitoring System

A similar test principle is used in StatStrip Glucose Hospital Meter System previously cleared under K132121.

5. Indications for Use

The Assure Titanium Blood Glucose Monitoring System consists of the Assure Titanium Blood Glucose meter and the Assure Titanium Blood Glucose test

strips. The Assure Titanium Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for *in vitro* diagnostic, point of care use in endocrinology clinics and nursing or skilled nursing facilities, for multiple patient use. This system should only be used with single-use, auto-disabling lancing devices for drawing finger stick capillary blood.

The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

The system is not intended for use in acute care or hospital settings.

The system is not intended for neonatal use.

The system is for prescription use only.

6. Substantial Equivalence Information

The Assure Titanium Blood Glucose Monitoring Device uses similar intended use as the predicate, StatStrip Glucose Hospital Meter System. Also, test principle and technology are similar for both devices. **Table 1** below provides a comparison between the Assure Titanium Blood Glucose Monitoring System and its predicate device.

As described in the performance testing summary below, the verification and validation (bench and clinical) testing successfully demonstrated substantial equivalence for the Assure Titanium Blood Glucose Monitoring System to the predicate device as required per 21 CFR § 807.92(b)(3).

Table 1: Similarities and Differences Table

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
510(k) Number	K200788	K132121
Device/Measuring System	Assure® Titanium Blood Glucose Monitoring System	StatStrip Glucose Hospital Meter System

COMPONENT/ CHARACTERISTIC	PROPOSED	PREDICATE
Intended Use and Indications for Use	The Assure Titanium Blood Glucose Monitoring System consists of the Assure Titanium Blood Glucose meter and the Assure Titanium Blood Glucose test strips. The Assure Titanium Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended for in vitro diagnostic, point of care use in endocrinology clinics and nursing or skilled nursing facilities, for multiple patient use. This system should only be used with single-use, auto-disabling lancing devices for drawing finger stick capillary blood. The system is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia. The system is not intended for use in acute care or hospital settings. The system is not	For the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood and neonate heel stick specimens. Also for the quantitative determination of glucose in venous whole blood, arterial whole blood, neonatal heel stick, and neonatal arterial whole blood throughout all hospital and all professional healthcare settings.

	intended for neonatal use. The system is for prescription use only.	
Population limitation	Not intended for neonatal use, acute care or hospital settings, nor for use with patients receiving intensive medical intervention/therapy.	Not intended for patients receiving intensive medical intervention/therapy. This system is intended for use with neonatal arterial whole blood but has not been validated for neonatal venous blood.
Sample Type	Fresh capillary whole blood*	Whole Blood: Capillary, Venous, Arterial, and Neonate arterial whole blood
Test Strip Ejector	Yes	No
Controls	3 levels of Assure Control- Control Solutions	3 levels of Nova StatStrip Control Solutions
Maximum Altitude	10,000 ft (3,048 meters)	15,000 ft (4500 meters)
Sample Volume	0.5 µL	1.2 µL
Weight	4.1 oz with batteries	9.6 oz
Dimensions	4.7 x 2.4 x 1.2 inch	6.0 x 3.25 x 1.8 inch
Battery/Power source	Two 1.5V alkaline AAA batteries	3.7V Li Polymer battery (Rechargeable/Replaceable)
Operating Temperature range	46-104^{0}F (8-40^{0}C)	59-104 ^{0}F (15-40^{0}C)
Hematocrit Range	10-70%	20-65%
Data Storage	1,000 test results	1,000 Patient Tests 200 QC Tests 4000 Operators
Measuring Time	7 seconds	6 seconds
Electrical Compliance	Conforms to ANSI/AAMI IEC 60601-1-2:2014	Conforms to: IEC 61010-1:2001 and IEC 61010-2-101:2002
Measuring Range	10-600 mg/dL	10-600 mg/dL

Relative Humidity	10-90% (no condensation)	10-90% (no condensation)
Enzyme	Glucose oxidase (*Aspergillus niger* sourced)	Glucose Oxidase (*Aspergillus* sourced)
Test Principle	Electro-chemical biosensor (Amperometric)	Electro-chemical biosensor (Amperometric)
Calibration	Automatic coded calibration	Automatic, no calibration code
Wi-Fi network connectivity	No	No

*Although whole blood samples are used for measurement, displayed results are equivalent to plasma glucose levels.

7. Summary of Performance Testing

Performance testing was conducted on the proposed Assure Titanium Blood Glucose Monitoring System in accordance with the FDA guidance *Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use*, 2016 and 2020 using final product. Performance testing demonstrated that the device meets the performance requirements for its intended use.

PRECISION

Within-run and intermediate precision for the Assure Titanium Blood Glucose Monitoring System were evaluated to assess imprecision of the system across the glucose measuring range and under normal use conditions.

Briefly, within-run precision was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to 5 glucose concentrations. These whole blood samples were tested on at least 10 vials of 3 test strip lots using at least 10 Assure Titanium Blood Glucose Meters. Test strips were taken from the same bottle for each meter. This resulted in 500 results on each lot, for a total of 1500 tests.

Results for the within-run precision testing are shown in **Table 2**, mean results for each glucose level are presented for each lot with associated standard deviation (SD), percent coefficient of variation (%CV) and the 95% confidence intervals.

Table 2: Within-Run Precision Results for Assure Titanium Blood Glucose Monitoring System

Lot #	Glucose Level (mg/dL)	Mean (mg/dL)	SD	95% CI	%CV
280-2	30-50	45.7	1.2	1.0 to 1.4	2.6%
	51-110	96.3	2.0	1.6 to 2.4	2.1%
	111-150	140.2	3.1	2.5 to 3.6	2.2%
	151-250	203.7	6.2	5 to 7.5	3.1%
	251-400	324.3	10.1	8.1 to 12.1	3.1%
280-4	30-50	44.4	1.3	1.0 to 1.5	2.9%
	51-110	95.7	2.0	1.6 to 2.4	2.1%
	111-150	139.6	2.8	2.2 to 3.3	2.0%
	151-250	204.9	3.8	3.1 to 4.6	1.9%
	251-400	324.2	7.5	6.1 to 9	2.3%
280-5	30-50	42.6	1.0	0.8 to 1.2	2.4%
	51-110	92.8	2.3	1.8 to 2.7	2.4%
	111-150	137.8	3.2	2.6 to 3.9	2.3%
	151-250	202.7	4.9	3.9 to 5.8	2.4%
	251-400	324.1	8.7	7 to 10.4	2.7%

The data in **Table 2** demonstrate the within-run precision met the overall acceptance criteria for %CV ≤ 4.2% for the Assure Titanium Blood Glucose Monitoring System.

Intermediate precision was evaluated using control solution adjusted to the same 5 glucose concentrations. Multiple operators tested the control solution over 10 days using at least 10 bottles of 3 test strip lots and 10 Assure Titanium meters. Test strips were taken from the same bottle for each meter. This resulted in 50 tests per lot per day for a total of 1500 tests.

Results for intermediate precision testing for all lots are shown in **Table 3**. Mean results for each glucose level are presented with associated standard deviation (SD), percent coefficient of variation (%CV) and the 95% confidence intervals.

Table 3: Intermediate Precision Results for Assure Titanium

	Glucose Level (mg/dL)	Mean (mg/dL)	SD	95% CI	%CV
All Lots Combined	30-50	42.4	0.8	0.6 to 0.9	1.9
	51-110	87.0	1.4	1.1 to 1.7	1.6
	111-150	129.3	1.8	1.4 to 2.1	1.4
	151-250	254.7	3.9	3.2 to 4.7	1.5
	251-400	360.6	7.5	6.0 to 9.0	2.1

The data in **Table 3** show that Intermediate precision met the overall acceptance criteria.

LINEARITY

Linearity for the Assure Titanium Blood Glucose Monitoring System was evaluated using glucose concentrations across the claimed glucose measuring range and data was analyzed according to CLSI EP6-A: *Evaluation of the Linearity of Quantitative Measurement: A Statistical Approach; An Approved Guideline*.

Briefly, linearity was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to eleven evenly spaced glucose concentrations. The target glucose concentrations were verified by the YSI 2300 reference analyzer. These whole blood samples were tested on 3 test strip lots using 5 Assure Titanium Blood Glucose Meters. This resulted in 5 replicates per level per lot tested, for a total of 165 results.

Data analysis included linear regression with regression equation and coefficient of determination (R^2) presented for each lot tested and presented in **Table 4**.

Table 4: Linear Regression Equation for All Assure Titanium Blood Glucose Monitoring System Lots

Lot	Linear Regression Equation	R^2
Type 280-1	y = 1.0079x + 3.9485	0.9988
Type 302-1	y = 1.0063x + 3.3727	0.9993
Type 302-2	y = 0.9902x + 2.1839	0.9999

Data analysis showed that linearity testing met the acceptance criteria in that all measurements fell within the ranges shown in **Table 5**, demonstrating linearity of the Assure Titanium Blood Glucose Monitoring System across the claimed measuring range of 10-600 mg/dL.

Table 5: Assure Titanium Blood Glucose Monitoring System Comparison to YSI 2300 Reference

Lot	Within ±15% at <75 mg/dL and ±12% at ≥75 mg/dL from reference
Type 280-1	100%
Type 302-1	100%
Type 302-2	100%

HEMATOCRIT

The effect of hematocrit on the performance of the Assure Titanium Blood Glucose Monitoring System was evaluated to establish that it can be safely used across the claimed hematocrit range. Briefly, percent hematocrit effect on Assure Titanium Blood Glucose Monitoring System results was evaluated using venous whole blood adjusted to five glucose levels and thirteen hematocrit levels spaced 5% apart spanning the claimed hematocrit range.

The target acceptance criteria are as follows: For glucose levels ≥ 75 mg/dL, the average bias to comparator method should be <5% with no individual value exceeding 10%. For glucose levels <75 mg/dL, the absolute bias should be reported with 95% confidence intervals justified for clinical impact.

The results for glucose levels ≥75 mg/dL met the target acceptance criteria. In addition, the absolute bias for results for glucose levels <75 mg/dL ranged from -1.5 to 2.2 mg/dL, an error so small that this error would not impact patient safety. The results of the Hematocrit Evaluation study support the safe use of the Assure Titanium Blood Glucose Monitoring System across the claimed hematocrit range of 10- 70% in the intended use population.

INTERFERENCE

The effect of potentially interfering endogenous and exogenous substances was evaluated on the Assure Titanium Blood Glucose Monitoring System. The study was designed using whole blood samples spiked or allowed to glycolyze to 3 target ranges. Eachinterferent was tested at clinically relevant concentrations. For each concentration of potential interferent, average percent bias to untreated control samples and 95% confidence intervals were calculated. If interference was observed additional testing was performed to determine the concentration at which the interference starts to occur. **Table 6** lists potentially interfering substances and the maximum concentrations tested and the highest tested concentration at which no interference was observed.

Table 6: Maximum Concentrations Tested

	Potential Interfering Substance	Highest concentration with no interference	Maximum Test Concentration
1	Acetaminophen	20 mg/dL	20 mg/dL
2	Ascorbic acid	4 mg/dL	6 mg/dL
3	Conjugated Bilirubin	50 mg/dL	50 mg/dL
4	Unconjugated Bilirubin	40 mg/dL	40 mg/dL
5	Cholesterol	500 mg/dL	500 mg/dL
6	Creatinine	15 mg/dL	15 mg/dL
7	Dopamine	20 mg/dL	20 mg/dL
8	EDTA	180 mg/dL	200 mg/dL
9	Galactose	60 mg/dL	60 mg/dL
10	Gentisic acid	700 mg/dL	1,000 mg/dL
11	Reduced Glutathione	92 mg/dL	92 mg/dL
12	Hemoglobin	20,000 mg/dL	20,000 mg/dL
13	Heparin	500 IU/dL	500 IU/dL
14	Ibuprofen	50 mg/dL	50 mg/dL

15	Icodextrin	1094.4 mg/dL	1094.4 mg/dL
16	L-Dopa	0.75mg/dL	0.75 mg/dL
17	Maltose	5,000 mg/dL	10,000 mg/dL
18	Methyl-L-dopa	1000 mg/dL	1000 mg/dL
19	Salicylic acid	60 mg/dL	60 mg/dL
20	Sodium	414 mg/dL	414 mg/dL
21	Tolbutamide	100 mg/dL	100 mg/dL
22	Tolazamide	40 mg/dL	40 mg/dL
23	Triglycerides	1,500 mg/dL	1,500 mg/dL
24	Uric acid	24 mg/dL	24 mg/dL
25	Xylose	300 mg/dL	600 mg/dL
26	Xylitol	0.09 mg/dL	0.09 mg/dL
27	Mannitol	1,800 mg/dL	1,800 mg/dL
28	Fenofibric Acid	1.8 mg/dL	1.8 mg/dL
29	Canagliflozin	15×10^{-4} mg/dL	15×10^{-4} mg/dL
30	Amlodipine Besylate	18×10^{-4} mg/dL	18×10^{-4} mg/dL
31	Atorvastatin Calcium	84×10^{-4} mg/dL	84×10^{-4} mg/dL
32	Cilostazol	21×10^{-2} mg/dL	21×10^{-2} mg/dL
33	Prasugrel	105×10^{-3} mg/dL	105×10^{-3} mg/dL
34	Nortriptyline HCl	45×10^{-6} mg/dL	45×10^{-6} mg/dL
35	Budesonide	36×10^{-5} mg/dL	36×10^{-5} mg/dL
36	Dextromethorphan	9×10^{-4} mg/dL	9×10^{-4} mg/dL
37	Oxcarbazepine	258×10^{-2} mg/dL	258×10^{-2} mg/dL
38	Trihexyphenidyl HCL	15×10^{-3} mg/dL	15×10^{-3} mg/dL
39	Fluphenazine Decanoate	81×10^{-5} mg/dL	81×10^{-5} mg/dL
40	Levoflaxicin	183×10^{-5} mg/dL	183×10^{-5} mg/dL
41	Glimiperide	576×10^{-4} mg/dL	576×10^{-4} mg/dL
42	Benazeprilat	297 nmol/dL	297 nmol/dL
43	Saxagliptin	72×10^{-4} mg/dL	72×10^{-4} mg/dL
44	Morphine	28.3 nmol/dL	84.9 nmol/dL
45	Ursodiol	$7{,}836\times10^{-4}$ mg/dL	$9{,}795\times10^{-4}$ mg/dL
46	Silodosin	1848×10^{-5} mg/dL	1848×10^{-5} mg/dL
47	Letrozole	31.2 nmol/dL	31.2 nmol/dL

The results were compared to the following target acceptance criteria: for each concentration of potential interferent the average percent bias and 95% confidence interval of test sample to untreated control sample must be within ±10% at each glucose level.

Interfering Substances

- Patients with high doses of Vitamin C intake (ascorbic acid; blood levels higher than 4 mg/dL) may yield inaccurate results.
- Patients undergoing oxygen therapy may yield inaccurate results.

CLEANING AND DISINFECTION VIRAL ELIMINATION EFFECTIVENESS

The cleaning and disinfection viral elimination effectiveness study for the Assure Titanium Blood Glucose Monitoring System was conducted by Microbac Laboratories (Sterling, VA).

The elimination of duck hepatitis B virus, as a surrogate for human hepatitis B virus, using the disinfection product, PDI Super Sanicloth (EPA# 9480-4), has been evaluated with the constituent surface materials of the Assure Titanium Blood Glucose Monitoring System.

The PDI Super Sanicloth Wipes were proven to be effective in eliminating the duck hepatitis B virus from all tested surfaces.

CLEANING AND DISINFECTION ROBUSTNESS/DURABILITY

Cleaning and disinfection durability testing were performed to demonstrate that the Assure Titanium Blood Glucose Monitoring System can withstand multiple cleaning and disinfection cycles to validate a three-year use life or "warranty" for the Assure Titanium Blood Glucose Monitoring System. The number of cleaning and disinfection cycles performed for this testing was based ten cleaning and disinfection cycles per day for three years for a total of 10,950 cycles (10 cycles/day * 365 days/year * 3 years = 10,950).

To demonstrate that the Assure Titanium Blood Glucose Monitoring System is not adversely affected by the recommended cleaning and disinfection cycles applied over a three-year use life, five meters were cleaned and disinfected 10,950 times with PDI Super Sanicloth Wipes (EPA# 9480-4) and examined to detect any performance issues and signs of physical deterioration.

A physical inspection and performance testing of each of the five meters was performed at the beginning of the study, midway through the study (approximately 5,480 cleaning anddisinfection cycles), and after the 10,950 cleaning and disinfection cycles were complete. The five meters were inspected at the three time points to determine if there were signs of physical and/or performance deterioration.

The venous blood performance met the acceptance criteria at each time point. All external material passed physical and performance inspection after cleaning and disinfecting 10,950 times with PDI Super Sanicloth Wipes.

INTERMITTENT SAMPLING

Intermittent sampling occurs when a short sample is applied to a test strip, a glucose measurement begins, and more sample is applied to the test strip before the glucose measurement is complete. Briefly, intermittent sampling was evaluated using venous whole blood spiked with high concentration glucose solution or allowed to glycolyze to three concentrations: 50-65 mg/dL, 100-120 mg/dL, 200-250 mg/dL. The glucose levels were verified by the YSI 2300 reference analyzer.

The results demonstrated that the Assure Titanium Blood Glucose Monitoring System provides accurate glucose measurements or an error when the sample is intermittently applied to an Assure Titanium Blood Glucose Test Strip.

ENVIRONMENTAL/SYSTEM OPERATING CONDITIONS

A study to assess the performance of the Assure Titanium Blood Glucose Monitoring System when used under various operating temperature and humidity conditions was performed. These studies were designed to represent actual use conditions experienced by Blood Glucose Monitoring System users. The tested temperature and humidity ranges covered the system operating conditions and also included ranges outside the claimed operating range. The testing incorporated eight extreme temperature and humidity combinations (high temperature/low humidity; high temperature/high humidity; low temperature/low humidity; low temperature/high humidity) within and outside the claimed operating range.

ALTITUDE

ARKRAY evaluated the effect of altitude on the performance of the Assure Titanium Blood Glucose Monitoring System. Three lots of Assure Titanium test strips were tested with venous blood samples at three glucose levels at two altitude conditions. Sea level (203 feet) and high altitude (10,000 feet) were tested using a custom-made pressure chamber to create the effects of altitude.

The results demonstrated that the Assure Titanium Blood Glucose Monitoring System performance is unaffected by altitudes up to and equal to an elevation of 10,000 feet.

ERROR CODES FOR SAMPLES OUTSIDE THE MEASURING RANGE

ARKRAY performed analyses to demonstrate that the Assure Titanium Blood Glucose Monitoring System provides the appropriate error codes when measured glucose concentrations are outside of the Blood Glucose Monitoring System's claimed measuring range. Three lots of Assure Titanium test strips were tested with venous blood samples at two glucose levels (<10 and >600 mg/dL). The acceptance criteria were as follows: All meters to display "Lo" at glucose levels <10 mg/dL, all meters to display "HI" at glucose levels >600 mg/dL.

All results met the acceptance criteria demonstrating that the Assure Titanium Blood Glucose Monitoring System will supply the user with the appropriate error codes when measuring blood glucose concentrations outside of the claimed measuring range.

ERROR CODES AND FLAGGING

ARKRAY performed evaluations to demonstrate that the Assure Titanium Blood Glucose Monitoring System provides error codes and flags according to the design specification. Please see **Table 7** below for details on the error codes/flags evaluated.

Table 7: Assure Titanium Blood Glucose Monitoring System Error Codes and Flags

E6	Occurs when the temperature is outside the temperature operating range
E5	Occurs when an abnormal sample is detected, the contact bars of the test strips are dirty, or an incorrect sample type is used
E0	Occurs when measurement of blood sample is attempted during QC lockout
Control Solution Flag	Meter displays control flag when control solution is tested
Temperature Flag	Occurs alongside E6 when the temperature is outside the temperature operating range

For each error code/flag listed in **Table 7**, the appropriate conditions that trigger the error code/flag were tested and the error code/flag was verified. Additionally, conditions that should not trigger the error code/flag were also tested and the absence of the error code/flag was verified.

SHORT SAMPLE DETECTION

Blood glucose measurement from short samples (samples of reduced sample volume) can lead to inaccurate results. To avoid the risk of inaccurate results, Blood Glucose Monitoring Systems should be able to detect that a short blood sample has been applied to the test strip and should not provide a result.

Three lots of Assure Titanium test strips were tested with venous blood samples at three glucose levels (50-65, 100-120, 200-250 mg/dL) that were verified using the YSI 2300. Approximately 0.1, 0.3, 0.5, 1, 5, or 10 µL of sample was applied to the test strip. Once the countdown was completed (if initiated), an error or the test result displayed on the meter.

The results demonstrated that the Assure Titanium Blood Glucose Monitoring System will either produce an error or an accurate result when short sampled.

SAMPLE PERTURBATION

Sample perturbation occurs when an appropriate volume of blood is applied to the test strip for glucose measurement, but an event such as wicking of blood away from the test strip, flicking of the test strip or flipping of the meter occurs during the start of the measurement and potentially alters the volume of the initial sample application.

Three lots of Assure Titanium test strips were tested with venous blood samples at three glucose levels (50-65, 100-120, 200-250 mg/dL) that were verified using the YSI 2300. The samples were applied to the test strip and then perturbed by flicking the test strip, flipping the meter on the side, and wicking the sample away using a tissue.

The results demonstrated that the Assure Titanium Blood Glucose Monitoring System either provides an error or an accurate result when the sample is perturbed.

TESTING WITH USED TEST STRIP

The Assure Titanium Blood Glucose Monitoring System is designed to automatically detect the insertion of used Assure Titanium Blood Glucose Test Strips into the Assure Titanium Blood Glucose Meter. Insertion of used Assure Titanium Blood Glucose Test Strips into the system should not provide glucose measurement results.

Three lots of Assure Titanium test strips were dosed with either capillary finger-stick blood or control solution. The used test strips were then re-inserted into Assure Titanium meters to produce an error. The target acceptance criteria are as follow: All used test strips shall produce the E1 error upon re-insertion. All test results met the acceptance criteria.

SUMMARY OF CLINICAL STUDY (METHOD COMPARISON)

The Assure Titanium Blood Glucose Meter and Assure Titanium Blood Glucose Test Strips for the Assure Titanium Blood Glucose Monitoring System were tested in a multi-center study conducted at one (1) nursing/skilled nursing facility and two (2) endocrinology clinics to demonstrate clinical performance with patients/subjects in whom routine glucose monitoring is done in these settings.

Nursing/skilled nursing facility (Site #1) is a 475-bed institution in the state of Massachusetts. The study took place across both long-term care nursing and temporary care/rehabilitation units. The study was conducted by Point-of-Care operators who took capillary blood samples from 130 patients. Patients in this study represented 390 medical conditions and 239 different medications. Site #2 is an endocrinology clinic located in the state of California. Point-of-Care operators took capillary blood samples from 165 patients. Patients in this study represented 18 medical conditions and 245 different medications. Site #3 is an endocrinology clinic located in the state of Georgia. Point-of-Care operators took capillary blood samples from 101 patients. Patients in this study comprised 61 medical conditions and 196 different medications.

In total, capillary blood samples from 396 patients were measured and the results were compared to the YSI Model 2300 Glucose Analyzer, a lab instrument (comparator method). The **tables 8-12** below show differences in glucose values between the Assure Titanium Blood Glucose Meter and the YSI method.

The slope, correlation, intercept, standard error, and 95% confidence interval as shown in **Table 8** represent a strong linear correlation between the Assure Titanium Blood Glucose Monitoring System and the YSI 2300 reference analyzer.

Table 8: Assure Titanium Blood Glucose Monitoring System Correlation

	Results obtained by healthcare professionals	
	Nursing/Skilled Nursing Facility	Endocrinology Clinic
Slope	0.98	0.98
Correlation 'r'	0.99	0.99
Intercept	3.24	2.83
Number of Samples	130	266
Range Tested	29.0 - 405.5 mg/dL	43.7 - 492.5 mg/dL

Table 9: Nursing/Skilled Nursing Facility Accuracy results for glucose concentrations <75 mg/dL:

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)	0/1 (0%)

Table 10: Nursing/Skilled Nursing Facility Accuracy results for glucose concentrations ≥75 mg/dL:

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ±5 %	Within ±10 %	Within ±12 %	Within ±15 %	Within ±20 %	Exceeds ±20 %
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	80/129 (62%)	122/129 (94.6%)	125/129 (96.9%)	128/129 (99.2%)	129/129 (100%)	0/129 (0%)

Table 11: Endocrinology Clinic Accuracy results for glucose concentrations <75 mg/dL:

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	17/26 (65.4%)	25/26 (96.2%)	26/26 (100%)	26/26 (100%)	0/26 (0%)

Table 12: Endocrinology Clinic Accuracy results for glucose concentrations ≥75 mg/dL:

Difference range between the true blood glucose level and the Assure Titanium Blood Glucose Monitoring System result	Within ±5 %	Within ±10 %	Within ±12 %	Within ±15 %	Within ±20 %	Exceeds ±20 %
The percent (and number) of samples for which the difference between the Assure Titanium Blood Glucose Meter and the YSI comparator method were within the difference range shown in the top row	163/240 (67.9%)	224/240 (93.3%)	230/240 (95.8%)	235/240 (97.9%)	240/240 (100%)	0/240 (0%)

Medications and Medical Conditions:

The clinical studies included patients representative of each clinical setting. A detailed analysis of medical conditions and medications was performed on the clinical data set from all three (3) clinical study sites to identify any potential safety issues with the use of the Assure Titanium Blood Glucose Monitoring System within the intended use population. A frequency distribution table (**Table 13**) for each Drug Class as well as a table for medical conditions (**Table 14**) are presented below.

Table 13: Medications Table

Assure Titanium Method Comparison Study Drug Table		
Therapeutic Drug Class 2	**Therapeutic Drug Class 3**	**Number of Patients**
Agents Acting on the Renin-Angiotensin System	ACE Inhibitors, Plain	107
	Angiotensin II Receptor Blockers (ARBs), Plain	62
Agents Acting on the Renin-Angiotensin System	Angiotensin II Receptor Blockers (ARBs), Combinations	11
All Other Therapeutic Products	All Other Therapeutic Products	13
Anabolic Agents for Systemic Use	Other Mineral Supplements	29
Analgesics	Opioids	66
	Other Analgesics and Antipyretics	132
Anesthetics	Anesthetics, General	1
	Anesthetics, Local	23
Antianemic Preparations	Iron Preparations	32
	Vitamin B12 and Folic Acid	42
Antibacterials for Systemic Use	Beta-Lactam Antibacterials, Penicillins	13
	Other Antibacterials	8
	Other Beta-Lactam Antibacterials	5
	Quinolone Antibacterials	7
	Sulfonamides	6
	Tetracyclines	1
Antibiotics and Chemotherapeutics for Determatological Use	Antibiotics for Topical Use	2
	Chemotherapeutics for Topical Use	1
Antidiarrheals, Intestinal Inflammatory/Antiinfective Agents	Antidiarrheal Microorganisms	10
	Antipropulsives	7
	Intestinal Adsorbents	1
	Intestinal Antiinflammatory Agents	35
	Other Antidiarrheals	2
Antiemetics and Antinauseants	Antiemetics and Antinauseants	19
Antiepileptics	Antiepileptics	110
Antifungals for Dermatologic Use	Antifungals for Systemic Use	1
	Antifungals for Topical Use	23
Antigout Preparations	Antigout Preparations	21
Antihistamines for Systemic Use	Antihistamines for Systemic Use	24
Antihypertensives	Antiadrenergic Agents, Generally Acting	5

	Antiadrenergic Agents, Peripherally Acting	6
	Arteriolar Smooth Muscle, Agents Acting on	8
	Other Antihypertensives	1
Antiinflammatory and Antirheumatic Products	Antiinflammatory and Antirheumatic Products, Non-Steroids	34
Antimycotics for Systemic Use	Antimycotics for Systemic Use	5
Antiobesity Preparations, Excl. Diet Products	Antiobesity Preparations, Excl. Diet Products	3
Anti-Parkinson Drugs	Anticholinergic Agents	2
	Dopaminergic Agents	16
Antiprotozoals	Agents Against Amoebiasis and Other Protozoal Diseases	1
	Antimalarials	5
Antiseptics and Disinfectants	Antiseptics and Disinfectants	1
Antithrombotic Agents	Antithrombotic Agents	237
Antivirals for Systemic use	Direct Acting Antivirals	5
Beta Blocking Agents	Beta Blocking Agents	147
	Beta Blocking Agents and Thiazides	1
Bile and Liver Therapy	Bile Therapy	1
Blood Substitutes and Perfusion Solutions	Irrigating Solutions	4
Calcium Channel Blockers	Selective Calcium Channel Blockers with Direct Cardiac Effects	16
	Selective Calcium Channel Blockers with Mainly Vascular Effects	64
Calcium Homeostasis	Anti-Parathyroid Agents	1
	Parathyroid Hormones and Analogues	1
Cardiac Therapy	Antiarrhythmics, Class I and III	10
	Cardiac Glycosides	6
	Cardiac Stimulants, Excl. Cardiac Glycosides	4
	Other Cardiac Preparations	5
	Vasodilators Used in Cardiac Diseases	11
Corticosteroids for Systemic use	Corticosteroids for Systemic use, Plain	4
Corticosteroids, Dermatological Preparations	Corticosteroids, Plain	10
Cough and Cold Preparations	Cough Suppressants, Excl. Combinations with Expectorants	16
	Expectorants, Excl. Combinations with Cough Suppressants	10
Digestives, Incl. Enzymes	Digestives, Incl. Enzymes	10

Diuretics	Aldosterone Antagonists and Other Potassium-Sparing Agents	20
	High-Ceiling Diuretics	53
	Low-Ceiling Diuretics, Excl. Thiazides	3
	Low-Ceiling Diuretics, Thiazides	45
Drugs for Acid Related Disorders	Antacids	1
	Drugs for Peptic Ulcer and Gastro-Oesophageal Reflux Disease (GORD)	133
Drugs for Constipation	Drugs for Constipation	307
Drugs for Functional Gastrointestinal Disorders	Belladonna and Derivatives, Plain	4
	Drugs for Functional Gastrointestinal Disorders	21
	Propulsives	7
Drugs for Obstructive Airway Diseases	Adrenergics, Inhalants	53
	Other Drugs for Obstructive Airway Diseases, Inhalants	54
	Other Systemic Drugs for Obstructive Airway Diseases	15
Drugs for Treatment of Bone Diseases	Drugs Affecting Bone Structure and Mineralization	12
Drugs Used in Diabetes	Blood Glucose Lowering Drugs, Excl. Insulins	359
	Insulins and Analogues	347
Ectoparasiticides, Incl. Scabicides, Insectides, and Repellents	Ectoparasiticides, Incl. Scabicides	1
Emollients and Protectives	Emollients and Protectives	1
Endocrine Therapy	Hormone Antagonists and Related Agents	3
	Hormones and Related Agents	5
Gynecological Antiinfectives and Antiseptics	Antiinfectives and Antiseptics, Excl. Combinations with Corticosteroids	4
Immunosuppressants	Immunosuppressants	12
Lipid Modifying Agents	Lipid Modifying Agents, Plain	263
Mineral Supplements	Calcium	20
	Other Mineral Supplements	29
	Potassium	24
Muscle Relaxants	Muscle Relaxants, Centrally Acting Agents	11
Nasal Preparations	Decongestants and Other Nasal Preparations for Topical Use	7
Ophthalmologicals	Antiglaucoma Preparations and Miotics	51

	Antiinfectives	3
	Antiinflammatory Agents	5
	Decongestants and Antiallergics	8
	Ocular Vascular Disorder Agents	1
	Other Ophthalmologicals	1
Other Alimentary Tract and Metabolism Products	Other Alimentary Tract and Metabolism Products	4
	Other Mineral Supplements	29
Other Dermatological Preparations	Other Dermatological Preparations	2
Other Drugs for Disorders of the Musculo-Skeletal System	Other Drugs for Disorders of the Musculo-Skeletal System	1
Other Nervous System Drugs	Drugs Used in Addictive Disorders	3
	Other Nervous System Drugs	1
	Parasympathomimetics	1
Pituitary and Hypothalamic Hormones and Analogues	Posterior Pituitary Lobe Hormones	1
Preparations for Treatment of Wounds and Ulcers	Cicatrizants	1
Psycholeptics	Antipsychotics	16
	Anxiolytics	48
	Hypnotics and Sedatives	58
Psychonaleptics	Anti-Dementia Drugs	12
	Antidepressants	147
	Psycholeptics and Psychanaleptics in Combination	8
	Psychostimulants, Agents Used for ADHD and Nootropics	13
Sex Hormones and Modulators of the Genital System	Androgens	6
	Estrogens	13
	Hormonal Contraceptives for Systemic Use	8
	Other Sex Hormones and Modulators fo the Genital System	2
	Progestogens	3
	Progestogens and Estrogens in Combination	1
Stomatological Preparations	Stomatological Preparations	1
Throat Preparations	Throat Preparations	2
Thyroid Therapy	Antithyroid Preparations	6
	Thyroid Preparations	96
Tonics	Other Mineral Supplements	29
Topical Products for Joint and Muscular Pain	Topical Products for Joint and Muscular Pain	3

Urologicals	Drugs Used in Benign Prostatic Hypertrophy	40
	Urologicals	18
Vasoprotectives	Agents for Treatment of Hemorrhoids and Anal Fissures for Topical Use	23
	Capillary Stabilizing Agents	1
Vitamins	Ascorbic Acid (Vitamin C), Incl. Combinations	19
	Calcium	20
	Multivitamins, Combinations	44
	Other Plain Vitamin Preparations	6
	Vitamin A and D, Incl. Combinations of the Two	123
	Vitamin B1, Plain and in Combination with Vitamin B6 and B12	7
	Vitamin B-Complex, Incl. Combinations	1

Table 14: Medical Conditions Table

Titanium Method Comparison Medical Conditions Table		
Condition Category	**Condition**	**Subjects w/ Medical Condition**
Auditory	Excessive Cerumen	3
	Hard of Hearing	19
	Ruptured Eardrum	1
Biliary	Cholangitis	3
	Cholecystectomy	3
	Cholecystitis	1
	Cholelithiasis	2
Cancer	Benign Neoplasm	1
	Bone Cancer	1
	Brain Cancer	1
	Breast Cancer	8
	Breast Cancer, Historical	4
	Colon Cancer	1
	Colon Cancer, Historical	2
	Hepatocellular Carcinoma	1
	Leukemia	1
	Lipoma	2
	Liver Cancer	1

	Lung Cancer	2
	Lymphatic Cancer	1
	Meningioma	2
	Multiple Myeloma	1
	Non-Hodgkin's Lymphoma	1
	Pancreatic Cancer	1
	Prostate Cancer	6
	Renal Cancer	4
	Renal Cancer, Historical	1
	Skin Cancer	4
	Skin Cancer, Historical	3
	Throat Cancer	1
	Thyroid Cancer	2
	Thyroid Cancer, Historical	1
Cardiac	Aortic Aneurysm	3
	Aortic Insufficiency	1
	Aortic Regurgitation	1
	Aortic Stenosis	9
	Arrhythmia	2
	Arteriosclerosis	2
	Atrial Fibrillation	32
	Bradycardia	5
	Bundle Branch Block	3
	Cardiovascular Disease	3
	Carotid Artery Occlusion	1
	Chest Pain	1
	Chronic Systolic Heart Failure	1
	Coronary Artery Disease	35
	Elevated Troponin	2
	Endocarditis	2
	Heart Block	2
	Heart Disease	7
	Heart Failure	41
	Heart Murmur	3
	Hypertension	248
	Hypotension	4
	Mitral Insufficiency	1
	Mitral Regurgitation	2
	Mitral Stenosis	1
	Mitral Valve Prolapse	2
	Myocardial Infarction	3
	Myocarditis	1

	Occlusion and Stenosis of Carotid Artery	1
	Palpitations	2
	Patent Foramen Ovale	2
	Premature Atrial Contraction	1
	Premature Ventricular Contractions	1
	Sick Sinus Syndrome	1
	Sinus Node Dysfunction	1
	Sleep Apnea	19
	Tachycardia	4
	Tricuspid Regurgitation	1
	Ventricular Arrhythmia	1
	Ventricular Outflow Obstruction	1
Dermatological	Abscess	3
	Asteototic Dermatitis	1
	Blepharitis	2
	Dermatitis	7
	Eczema	4
	Erythema	1
	Foot Complications	39
	Intertrigo	2
	Pruritic Disorder	1
	Pruritus	5
	Psoriasis	2
	Rosacea	2
	Seborrheic Dermatitis	3
	Seborrheic Keratosis	4
	Skin Complications	21
	Skin Infection	3
	Skin Ulcer	29
	Tinea Pedis	3
	Tinea Versicolor	1
Endocrine	Adrenal Insufficiency	1
	Adrenal Nodule	1
	Gynecomastia	1
Gastro-Intestinal	Acid Reflux	1
	Celiac Disease	1
	Colitis	2
	Colon Polyp	2
	Constipation	68
	Diarrhea	15
	Diverticulitis	1
	Diverticulosis	1

	Gastroenteritis	1
	Gastroesophageal Reflux Disease	51
	Gastrointestinal Hemorrhage	2
	Gastro-Intestinal Problems	34
	Heartburn	1
	Incontinence	26
	Indigestion	2
	Irritable Bowel Syndrome	4
	Irritable Colon	1
	Ischemic Colitis	1
	Malabsorption Syndrome	1
	Nausea	6
	Pancreatitis	2
	Peptic Ulcer	3
	Rectal Prolapse	1
	Ulcer	1
	Vomiting	5
Hepatic	Bilirubinemia	1
	Cirrhosis	1
	Elevated INR	1
	Fatty Liver	2
	Hepatitis	1
	Hyperbilirubinemia	2
	Hypoalbuminemia	7
	Liver Dysfunction	2
	Subtherapeutic INR	1
	Supratherapeutic INR	1
	Transaminitis	1
Hormonal	Hyperprolactinemia	1
	Hypogonadism	3
	Polycystic Ovarian Syndrome	2
Immune	Arthritis	12
	Bacteremia	1
	Bacterial Infection	3
	Candida Infection	3
	Cellulitis	2
	Cold Sores	1
	Crohn's	1
	Eosinophilia	1
	Fever	7
	Gout	19
	Herpes Zoster	1

	Idiopathic Thrombocytopenic Purpura	1
	Immunodeficiency	1
	Immunosuppression	1
	Joint Inflammation	1
	Leukocytosis	16
	Leukopenia	1
	Lichen Planus	1
	Lymphadenitis	1
	Lymphedema	1
	Myasthenia Gravis	2
	Myelodysplastic Syndrome	1
	Oligoarthritis	1
	Onychomycosis	3
	Paronychia	1
	Photosensitivity	1
	Plantar Fasciitis	1
	Polymyalgia Rheumatica	2
	Rheumatoid Arthritis	10
	Sepsis	2
	Septic Arthritis	1
	Sjogrens Syndrome	1
	Verruca	1
Lipid Disorder	Dyslipidemia	11
	Hyperlipidemia	126
Metabolic	Diabetic Ketoacidosis	1
	Gestational Diabetes	1
	Hemochromatosis	1
	Hereditary Coproporphyria	1
	Hypercalcemia	4
	Hypercholesteremia	2
	Hypercholesterolemia	1
	Hyperglycemia	2
	Hyperkalemia	6
	Hypernatremia	3
	Hyperuricemia	1
	Hypocalcemia	1
	Hypoglycemia	5
	Hypokalemia	16
	Hypomagnesemia	6
	Hyponatremia	13
	Malnutrition	15
	Microalbuminuria	1

	Obesity	12
	Tumoral Calcinosis	1
	Vitamin Deficiency	42
	Weight Gain	5
	Weight Loss	19
Musculoskeletal	Achalasia	1
	Bursitis	3
	Cervical Spondylosis	3
	Contracture	1
	Degenerative Disc Disease	2
	Degenerative Spondylolisthesis	1
	Dysarthria	2
	Dystonia	1
	Esophageal Dysmotility	1
	Hernia	7
	Kyphosis	2
	Leg Cramp	1
	Monoclonal Gammopathy of Unknown Significance	2
	Muscle Spasms	2
	Muscle Weakness	8
	Muscular Dystrophy	1
	Myalgia	1
	Myositis	1
	Osteoarthritis	36
	Osteomyelitis	6
	Osteopenia	3
	Osteoporosis	24
	Pancytopenia	3
	Polyarthralgia	2
	Scoliosis	2
	Spinal Stenosis	15
	Temporomandibular Joint Syndrome	1
	Tendinitis	2
Neurological	Agitation	2
	Alzheimer's	14
	Amnesia	1
	Anorexia	4
	Anxiety	27
	Autonomic Neuropathy	1
	Bipolar Disorder	2
	Carpal Tunnel	3
	Cervical Radiculopathy	1

	Cervicalgia	1
	Chronic Hypomanic	1
	Chronic Pain	60
	Claustrophobia	1
	Cognitive Impairment	29
	Concussion	1
	Cord Compression	1
	Delirium	12
	Delusions	2
	Dementia	32
	Depression	45
	Diplegia	1
	Dizziness	6
	Dysautonomia	1
	Dysphagia	27
	Dysphonia	1
	Dysthymia	1
	Encephalopathy	12
	Essential Tremor	2
	Excoriation	1
	Fibromyalgia	2
	Globus Sensation	1
	Hallucinations	2
	Headache	1
	Lumbar Radiculopathy	2
	Memory Issues	2
	Migraine	2
	Mood Disorder	1
	Motor Skill Impairment	11
	Myoclonus	1
	Narcolepsy	1
	Neuralgia	2
	Neurologic Neglect Syndrome	1
	Neuropathy	98
	Nicotine Addiction	1
	Obsessive Compulsive Disorder	1
	Orthostatic Hypertension	1
	Orthostatic Hypotension	11
	Palsy	1
	Panic Attacks	1
	Parkinson's	7
	Polyneuropathy	4
	Post-Traumatic Stress Disorder	1

	Postural Orthostatic Tachycardia Syndrome	1
	Radicular Syndrome	1
	Schizophrenia	1
	Sciatica	2
	Seizures	4
	Somnolence	1
	Syrinx of Spinal Cord	1
	Tardive Dyskinesia	1
	Tremor	1
	Vascular Dementia	3
	Vasovagal Syncope	1
	Vertigo	4
None	None	50
Ocular	Blindness	10
	Bullous Keratopathy	1
	Cataract	15
	Conjunctivitis	4
	Dry Eye	7
	Glaucoma	22
	Macular Degeneration	6
	Macular Edema	1
	Pseudophakia	2
	Retinopathy	1
	Vision Problems	78
	Visual Impairment	1
Oral	Dental Abscess	1
	Gingival Bleeding	1
	Xerostomia	4
Other	Abnormal Gait	26
	Apathy	1
	Ascites	1
	Balance Issues	45
	Debility	53
	Dehydration	3
	Fatigue	3
	Frailty Syndrome	4
	Hyperproteinemia	1
	Hypothermia	1
	Impaired Mobility	1
	Insomnia	53
	Lethargy	4
	Mobility Issues	1

	Organ Prolapse	3
	Overweight	1
	Polypharmacy	6
	Polytrauma	1
	Sequela	1
Pancreatic	Intraductal Papillary Mucinous Neoplasm	1
Renal	Acute Kidney Disease	28
	Chronic Kidney Disease	53
	Diabetes Insipidus	1
	Elevated Alkaline Phosphatase	1
	Elevated Uric Acid	1
	Hematuria	6
	Hepatorenal Syndrome	1
	Hyperosmolality	1
	Interstitial Nephritis	1
	Kidney Disease	49
	Nephrolithiasis	1
	Nephropathy	1
	Renal Mass	1
	Tubulointerstitial Disease	1
Reproductive	Benign Prostatic Hyperplasia	17
	Endometriosis	1
	Enlarged Prostate	2
	Impotence	25
	Prostatitis	1
Respiratory	Allergic Rhinitis	6
	Asthma	12
	Bronchiectasis	2
	Bronchitis	1
	Chronic Obstructive Pulmonary Disease	10
	Cough	17
	Dyspnea	2
	Hypercarbia	2
	Lung Disease	1
	Pickwickian Syndrome	1
	Pleural Effusion	2
	Pneumonia	13
	Pneumonitis	1
	Pulmonary Edema	5
	Pulmonary Embolism	1
	Pulmonary Fibrosis	1
	Pulmonary Infection	1

	Pulmonary Mycobacterial Infection	1
	Pulmonary Nodules	2
	Respiratory Failure	9
	Restrictive Lung Disease	1
	Shortness of Breath	1
	Sinusitis	2
	Upper Respiratory Infection	1
Thyroid	Diaphoresis	1
	Goiter	6
	Hashimoto's	4
	Hyperparathyroidism	4
	Hyperthyroidism	5
	Hypoparathyroidism	1
	Hypothyroidism	60
	Thyroid Disorder	2
	Thyroid Nodule	5
Urinary	Bacteriuria	1
	Bladder Diverticulus	1
	Cystitis	1
	Dysuria	6
	Frequent Urination	3
	Overactive Bladder	5
	Urinary Retention	15
	Urinary Tract Infection	25
Vascular	Anemia	65
	Aneurysm	4
	Arterial Embolism	1
	Artery Stenosis	2
	Atherosclerosis	3
	Cerebral Artery Syndrome	1
	Cerebral Microvascular Disease	1
	Cerebral Vascular Accident	9
	Cerebrovascular Disease	3
	Coagulopathy	2
	Contusion	3
	Deep Vein Thrombosis	3
	Edema	33
	Epistaxis	1
	Gangrene	2
	Hematoma	4
	Hemorrhage	6
	Hemorrhoids	11
	Hypocapnia	1

	Hypoxemia	6
	Hypoxia	6
	Ischemia	1
	Methemoglobinemia	1
	Peripheral Vascular Disease	16
	Pulmonary Vascular Congestion	1
	Purpura	2
	Stroke	30
	Swelling	3
	Syncope	1
	Thalassemia	1
	Thrombocytopenia	14
	Thrombocytosis	4
	Thrombosis	1
	Transient Ischemic Attack	3
	Varicose Veins	1
	Venous Insufficiency	5
	Venous Ulcer	2

ACCURACY AT EXTREMES

An Accuracy at Extremes study was executed to conduct a more robust evaluation between Assure Titanium Blood Glucose Monitoring System and the Yellow Springs Instrument (YSI) 2300 reference analyzer in the extreme upper and lower claimed blood glucose measuring range using a POC operator.

Capillary samples were collected and allowed to glycolyze or were spiked with high concentration glucose solution to acquire 100 samples for testing with the Assure Titanium Blood Glucose Monitoring System and the comparator: YSI 2300. There were 50 samples with glucose <80 mg/dL and 50 with glucose >300 mg/dL.

The data for the Accuracy at Extremes Glucose Values study are presented in **Table 15** below.

Table 15: Accuracy at extreme glucose value results for Assure Titanium Blood Glucose Monitoring System vs YSI 2300 Reference Analyzer

Glucose Concentrations <80 mg/dL				
Within ±5 mg/dL	Within ±10 mg/dL	Within ±12 mg/dL	Within ±15 mg/dL	Exceeds ±15 mg/dL
43/50 (86%)	49/50 (98%)	50/50 (100%)	50/50 (100%)	0/50 (0%)

Glucose Concentrations >300 mg/dL					
Within ±5%	Within ±10%	Within ± 12%	Within ± 15%	Within ±20%	Exceeds ±20%
32/50 (64%)	46/50 (92%)	50/50 (100%)	50/50 (100%)	50/50 (100%)	0/50 (0%)

The results from this study demonstrated the proposed Assure Titanium Blood Glucose Monitoring System provides highly accurate glucose results when testing in the extreme glucose ranges.

USABILITY

A POC operator evaluation study was conducted during the clinical trial to evaluate the ease of use/understanding of the Assure Titanium Blood Glucose Monitoring System. The POC operator study involved POC operators filling out two usability questionnaires; one concerning the ease of use of the blood glucose meter system and one the ease of understanding of the Assure Titanium User Manual and the Quick Reference Guide (QRG). All the responses (100% combined) were positive i.e., Very Easy, Easy, or OK and indicated that the Assure Titanium Blood Glucose Monitoring System is easy to use. The overall rating of understanding the Quick ReferenceGuide and User Manual for Assure Titanium Blood Glucose Monitoring System was positive with participants rating 100% in categories of Very Easy, Easy or OK (combined).

Expected Values

Expected values for non-diabetics
Expected blood glucose values for non-pregnant adults without diabetes1
Fasting* <100 mg/dL
2 hours after meals <140 mg/dL

*Fasting is defined as no caloric intake for at least eight hours. Consult the patient's physician to determine the range that is appropriate for your patients.

1. American Diabetes Association. Standards of medical care in diabetes- 2021.
Diabetes Care. 2021;44(1)pS17."

8. Proposed Labeling

Labeling adequately communicates device intended use, safety precautions and directions for use. It satisfies 21 CFR 809.10 requirements for *in vitro* diagnostic devices.

9. Conclusion

The information provided in this 510(k) premarket notification supports the Assure Titanium Blood Glucose Monitoring System is substantially equivalent to the predicate, StatStrip Glucose Hospital Meter System.