December 6, 2023

Qurasense
% Richard Lewis, Senior Regulatory Device and Biologics Expert
Hyman, Phelps & McNamara P.C.
700 13th Street NW, Suite 1200
Washington, District of Columbia 20005

Re: K231465
Trade/Device Name: Q-Pad Test System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, QZG
Dated: May 19, 2023
Received: May 19, 2023

Dear Richard Lewis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joshua Balsam -S

Joshua M. Balsam, Ph.D.
Branch Chief
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)*
K231465

Device Name
Q-Pad Test System

Indications for Use *(Describe)*
The Q-Pad Test System is comprised of the Q-Pad Kit and the Q-Pad A1c Test.

The Q-Pad Kit is an in vitro diagnostic specimen collection and storage device intended for the collection of menstrual blood samples by individuals 18 years and older for subsequent analysis by an assay validated for use with the Q-Pad menstrual pad.

The Q-Pad A1c Test is an in vitro diagnostic device for the quantitative measurement of Hemoglobin A1C using menstrual whole blood collected onto filter paper using the Q-Pad Kit. The Q-Pad A1c Test is for the measurement of HbA1c on whole menstrual blood which will be self-collected by lay users at home and shipped to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term control of blood sugar (glucose) in women with diabetes.

This test is not to be used to diagnose or screen for diabetes.

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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510(k) Summary for k231465

Date of Summary: December 6th, 2023

Product Name: Q-Pad Test System

Sponsor: Qurasense
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Menlo Park, CA 94025
United States

Correspondent: Richard A. Lewis

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The Q-Pad Test System consists of the following:

Proprietary Name: Q-Pad A1c Test
Common Name: Glycosylated hemoglobin assay
Classification Name: Assay, glycosylated hemoglobin
Regulation Number: 21 CFR §864.7470
Product Code: LCP

Proprietary Name: Q-Pad Kit
Common Name: Blood specimen collection device
Classification Name: Menstrual Blood Collection Device
Regulation Number: 21 CFR §862.1675
Product Code: QZG

Substantial Equivalency

Qurasense's Q-Pad Test System has technological characteristics that are substantially equivalent to the predicate device identified in the table below. Both the proposed device and the predicate device provide the patient a method to collect a sample at home, mail the sample to the clinical laboratory, and later receive a report showing the measured Hemoglobin A1c.

Among the components included with the Q-Pad Test System is the collection device, Q-Pad, a menstrual pad that contains filter paper. Once the Q-Pad is received in the clinical laboratory, the dried blood sample is punched, eluted, and tested using FDA-cleared laboratory reagent and analysis systems, specifically the Beckman Coulter AU480 clinical chemistry device. The technological characteristics and intended use are substantially equivalent to the predicate device as summarized in the following table:

Description	**Subject Device** Q-Pad Test System	**Predicate Device** Home Access A1c Test K141944
Intended Use	Whole blood quantitative measurement of Hemoglobin A1c.	Whole blood quantitative measurement of Hemoglobin A1c.
Indications for use	The Q-Pad Test System is comprised of the Q-Pad Kit and the Q-Pad A1c Test. The Q-Pad Kit is an in vitro diagnostic specimen collection and storage device intended for the collection of menstrual blood samples by individuals 18 years and older for subsequent analysis by an assay validated for use with the Q-Pad menstrual pad. The Q-Pad A1c Test is an in vitro diagnostic device for the quantitative measurement of Hemoglobin A1c using menstrual whole blood collected onto filter paper using the Q-Pad Kit. The Q-Pad A1c Test is for the measurement of HbA1c on whole menstrual blood which will be self-collected by lay users at home and shipped to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term	The Home Access® A1C Test is an in vitro test method for the quantitative measurement of Hemoglobin A1c using capillary blood collected from the fingertip, collected onto filter paper via the Home Access collection cassette. The Home Access A1C Test is for measurement of HbA1c on blood specimens which can be collected at the patient's home or in a healthcare professional setting and delivered to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term control of blood sugar (glucose) in people with diabetes. This test is not to be used to diagnose or screen for diabetes. Not for use on neonates.

Description	**Subject Device** Q-Pad Test System	**Predicate Device** Home Access A1c Test K141944
	control of blood sugar (glucose) in women with diabetes. This test is not to be used to diagnose or screen for diabetes.	
Prescription/ Over-the- counter use	Over the counter	Prescription and Over the counter
Usage	Single Use	Single Use
Collect Sample At Home	Yes	Yes
Whole Blood Sample	Yes	Yes
Collection Kit Components	(2) Q-Pads Sample Container Instructions for Use Prepaid return Mailer Outer Packaging Patient Information Card	Blood sample collection Cassette Sample Pouch Sterile Safety Lancets Gauze Pad Bandage Instructions for Use Prepaid return Mailer Patient Info Card Outer Packaging
Send Samples to CLIA certified lab	Yes. Samples can only be sent and analyzed at Qurasense's CLIA-certified laboratory (Qvin Labs).	Yes. Samples sent to Home Access Health Corporation laboratory facility.
Analysis	Beckman Coulter A1c reagents Beckman Coulter device AU480	Beckman Coulter A1c reagents Beckman Coulter device AU640e (formerly Olympus)
Return Results	Yes, via mobile app or email.	Yes, mailed to the user.

Description	Subject Device Q-Pad Test System	Predicate Device Home Access A1c Test K141944
Precision	% CV < 2.44 %	% CV ≤ 3.9%
Measuring Range	4.0% to 15.0% HbA1c	4.5 – 14.5% HbA1c

Indication for Use

The Q-Pad Test System is comprised of the Q-Pad Kit and the Q-Pad A1c Test.

The Q-Pad Kit is an in vitro diagnostic specimen collection and storage device intended for the collection of menstrual blood samples by individuals 18 years and older for subsequent analysis by an assay validated for use with the Q-Pad menstrual pad.

The Q-Pad A1c Test is an in vitro diagnostic device for the quantitative measurement of Hemoglobin A1C using menstrual whole blood collected onto filter paper using the Q-Pad Kit. The Q-Pad A1c Test is for the measurement of HbA1c on whole menstrual blood which will be self-collected by lay users at home and shipped to the laboratory by mail. Measurements obtained through this method can be used for monitoring the long-term control of blood sugar (glucose) in women with diabetes.

This test is not to be used to diagnose or screen for diabetes.

Methodology

The Q-Pad menstrual pad (also referred to as "Q-Pad") is a modified menstrual pad which looks, feels, and is used like a normal menstrual pad. The Q-Pad has an embedded blood collection strip (Q-Strip) which can easily be removed and shipped for analysis at a laboratory. Instructions for use and results are presented in a HIPAA compliant mobile application.

Performance Data

Sample Matrix Equivalency

A CLSI EP35 based study was conducted to assess the sample matrix equivalency between venous blood and menstrual blood collected on the Q-Pad. Forty (40) paired (venous and menstrual blood) samples, that span the Analytical Measurement Range (AMR) of the assay, were tested. The regression analysis between venous and menstrual blood resulted in a slope of 0.969 (95% CI 0.944-0.994), an intercept of 0.181 (95% CI -0.017 to 0.380) and a R^2 of 0.997. The systematic difference between specimens at the 6.5 %HbA1c predetermined medical decision point (MDP) was 0.3% (the absolute systemic difference

between the specimens being 0.02) and the 95% confidence interval was 6.42 to 6.54 %HbA1c. The study results demonstrated that venous blood and menstrual DBS are equivalent sample types for measurement of HbA1c.

Precision using venous blood

A venous blood precision study was performed according to CLSI EP05-A3. Whole blood from four participants with known A1c levels of around 5%, 6.5%, 8% and 12% was obtained. A total of 320 samples were run. Each HbA1c level was tested in duplicate, twice a day for a total of 20 days (N = 80 per level). Overall, within-run, and within-day precision results were evaluated in the presence of multiple lots of reagents. Operator-to-operator precision was also assessed (Tables 1-3). Overall, the studies show an imprecision of no greater than 2.56% (acceptance criterion ≤ 4%).

Table 1. Precision/Reproducibility Data Summary - venous blood

	Mean	**Repeatability (within run)**		**Between run**		**Repeatability (within day)**		**Between day**		**Total**	
Sample	**%HbA1c**	**SD**	**%CV (95%CI)**	**SD**	**%CV (95%CI)**	**SD**	**%CV (95%CI)**	**SD**	**%CV (95%CI)**	**SD**	**%CV**
Low A1c	5.21 %	0.05	0.87 (0.58,1.15)	0.04	0.84 (0.82,1.24)	0.06	1.13 (0.74, 1.53)	0.08	1.61 (1.21, 2.01)	0.10	1.99
Elevated A1c	6.70%	0.06	0.88 (0.57, 1.19)	0.06	0.87 (0.84, 1.28)	0.08	1.21 (0.91, 1.51)	0.09	1.41 (1.11, 1.71)	0.12	1.82
High A1c	8.30%	0.08	0.93 (0.75, 1.11)	0.07	0.82 (0.78, 1.20)	0.10	1.15 (0.92, 1.38)	0.13	1.61 (1.37, 1.84)	0.16	1.91
Very High A1c	12.74%	0.13	1.03 (0.77, 1.29)	0.10	0.81 (0.76,1.19)	0.16	1.22 (0.86, 1.57)	0.27	2.14 (1.78, 2.49)	0.31	2.44

Table 2. Precision summary for samples run with different lots of each reagent - venous blood

		Different HbA1c reagent kit lots			**Different hemolysis reagent lots**		
		%HbA1c mean	**Total imprecision**		**%HbA1c mean**	**Total imprecision**	
Sample	**%HbA1c**		**SD**	**%CV (95%CI)**		**SD**	**%CV (95%CI)**
Low A1c	5.21	5.21	0.07	1.26 (1.10, 1.43)	5.21	0.01	0.20 (0.18, 0.23)
Elevated A1c	6.70	6.71	0.08	1.24 (1.03, 1.44)	6.70	0.04	0.57 (0.47, 0.66)
High A1c	8.30	8.30	0.10	1.20 (0.95, 1.45)	8.28	0.09	1.06 (0.84, 1.28)
Very High A1c	12.74	12.75	0.18	1.43 (0.97, 1.89)	12.72	0.10	0.79 (0.54, 1.04)

Table 3. Precision summary for samples run with different operators - venous blood

Sample	Operator 1	Operator 2	Operator 1	Operator 2	Operator 1	Operator 2	Operator to Operator
	%HbA1c mean	%HbA1c mean	SD	SD	%CV (95%CI)	%CV (95%CI)	%CV (95%CI)
Low A1c	5.19	5.25	0.08	0.08	2.04 (2.01, 2.07)	1.54 (1.50, 1.58)	1.88 (1.85, 1.92)
Elevated A1c	6.69	6.73	0.12	0.11	1.86 (1.83, 1.89)	1.66 (1.60, 1.72)	1.98 (1.94, 2.02)
High A1c	8.28	8.38	0.15	0.17	1.81 (1.78, 1.85)	1.98 (1.90, 2.07)	1.96 (1.91, 2.02)
Very High A1c	12.71	12.83	0.33	0.24	2.56 (2.48, 2.64)	1.83 (1.72, 1.95)	1.80 (1.72, 1.87)

Precision using menstrual blood

A precision study using Q-Pad collected menstrual DBS samples was performed according to CLSI EP05-A3. Three participants with a low, mid and high HbA1c level collected samples using the Q-Pad Kit. Samples were collected, shipped and processed according to the IFU. The samples were tested in duplicate, two times a day, over five days (N = 20 per level). Within-day-run, and between day-run precision results were evaluated (Table 4). Overall, the study shows an imprecision of no greater than 3.59% (acceptance criterion ≤ 4%).

Table 4. Precision/Reproducibility Data Summary - menstrual blood

	Mean	Repeatability (within run)		Between run		Repeatability (within day)		Between day		Total	
Sample	%HbA1c	SD	%CV (95%CI)	SD	%CV (95%CI)	SD	%CV (95%CI)	SD	%CV (95%CI)	SD	%CV
Low A1c	5.28%	0.07	1.33 (0.41, 2.24)	0.04	0.79 (0.72, 1.02)	0.11	2.01 (0.87, 3.15)	0.17	3.21 (1.59, 4.82)	0.19	3.59
Elevated A1c	7.63%	0.10	1.32 (0.76, 1.87)	0.00	0.05 (0.04, 0.06)	0.11	1.43 (0.97, 1.89)	0.14	1.83 (1.18, 2.48)	0.16	2.15
High A1c	12.35%	0.09	0.72 (0.08, 1.36)	0.06	0.47 (0.40, 0.63)	0.14	1.11 (0.40, 1.75)	0.15	1.22 (0.32, 2.12)	0.20	1.60

Lot-to-Lot Precision

Lot-to-lot accuracy and precision were evaluated as part of the method comparison study and shelf-life studies. During the method comparison study, three lots were distributed randomly to study participants. Table 5 compares the accuracy between the multiple lots of the Q-Pad Kit across 4 HbA1c levels.

Table 5. Passing-Bablok Estimates per Lot (method comparison study)

	Slope (95%CI)	Intercept (95%CI)
Lot 1	1.000 (0.975, 1.032)	-0.020 (-0.228, 0.182)
Lot 2	0.983 (0.957, 1.010)	0.072 (-0.097, 0.239)
Lot 3	1.027 (0.989, 1.066)	-0.212 (-0.471, 0.063)

Multiple lots of the Q-Pad Kit were used during shelf-life studies. A summary of the precision data from the shelf-life studies is presented in Table 6.

Table 6. Accelerated and Open-pouch Shelf Life lot precision data

	Accelerated Shelf Life	Open-Pouch Shelf Life
HbA1c Level	Average %CV (95%CI)	Average %CV (95%CI)
Low A1c	1.03 (0.06, 2.00)	0.44 (0.00, 1.58)
Elevated A1c	1.50 (0.00, 3.68)	0.90 (0.00, 1.97)
High A1c	1.40 (0.37, 2.42)	0.31 (0.17, 0.45)
Very High A1c	0.84 (0.00, 2.75)	1.45 (0.09, 2.81)

The lot-to-lot analysis in the method comparison, combined with the analysis from two controlled shelf-life studies demonstrated negligible risk of imprecision due to different lots.

Intra- and Inter-Strip Precision Flex studies

Additional flex studies were performed to assess imprecision from various locations on a Q-Strip (intra-strip) and between two Q-Strips (inter-strip).

Intra-strip Precision

The purpose of this study was to evaluate intra-strip (punch-to-punch) imprecision. Nine (9) participants were enrolled based on anticipated A1c levels. For each sample, three punches were selected by the operator and analyzed. Punches 2 and 3 were compared to the measured value of the first punch. Bias and %CV were calculated. Acceptance criteria was <10% bias of punches 2 and 3 when compared to the first punch and an average imprecision of <3.9% between the punches.

A maximum bias of 4.90% was recorded with a maximum CV between punches of 2.92% (Table 7).

Table 7. Intra-Strip Precision

Sample	Participant 1 %CV	Participant 2 %CV	Participant 3 %CV	SD (%)	%CV (95% CI)
Low A1c	0.94	0.81	1.71	0.49	1.15 (0.00, 2.36)
Mid A1c	1.17	2.92	1.18	1.01	1.75 (0.00, 4.26)
High A1c	1.72	0.90	0.62	0.49	1.08 (0.00, 2.30)

Inter-strip Precision

Inter-strip precision was evaluated by comparing results from two Q-Pads, both used during the same collection event. Nine (9) participants were enrolled based on anticipated A1c levels. Each Q-Strips was punched once and the resulting values were compared. Acceptance criteria was <10% bias and an average imprecision of <3.9% between Q-Strip samples.

A maximum bias of 3.92% and a maximum %CV of 2.72 was measured (Table 8).

Table 8. Inter-Strip Precision

Sample	Participant 1 %CV	Participant 2 %CV	Participant 3 %CV	SD (%CV)	%CV (95% CI)
Low A1c	0.76	0.41	0.14	0.31	0.44 (0.00, 1.22)
Mid A1c	2.72	2.70	2.34	0.21	2.59 (2.06, 3.11)
High A1c	0.87	0.35	0.10	0.39	0.44 (0.00, 1.41)

Linearity menstrual blood

A CLSI EP06-A based linearity study was performed on the Q-Pad Test System using known interval methodology. High and low %HbA1c menstrual DBS samples were extracted and then serially diluted to create a nine-member known interval menstrual blood panel that ranged from 4.47 to 14.5 %HbA1c. Data was analyzed using linear regression and polynomial fit analysis. A linear regression graph of the resulting data is presented in Figure 1, and results of a polynomial fit analysis are shown in Table 9.

Figure 1. Plot of %HbA1c results vs. reference %HbA1c values.

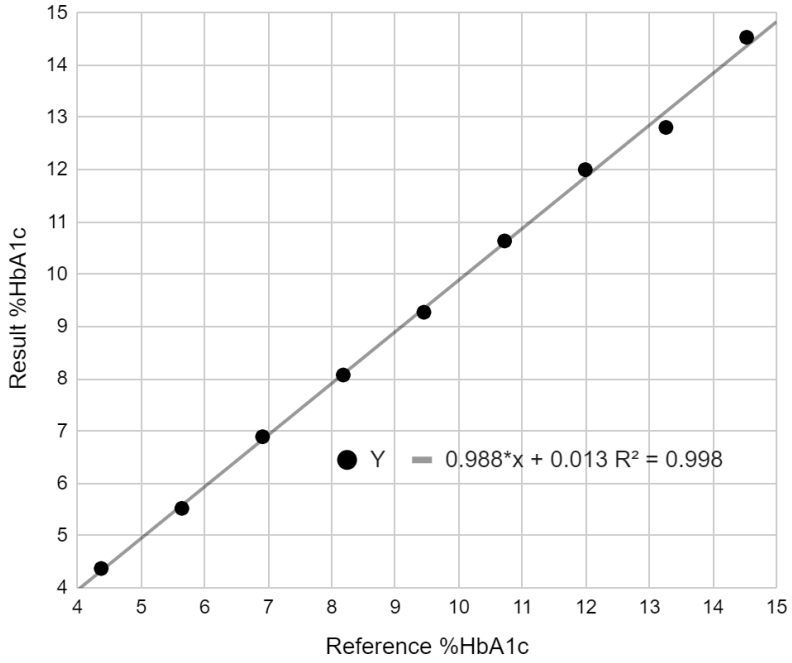

Table 9. Polynomial Fit Analysis (*statistically equivalent to zero)

Polynomial	Constant (T statistic)	X (T statistic)	X^2 (T statistic)	X^3 (T statistic)	Std Error of Estimate (%)	"Best" Polynomial
Line	*3.074 (42.5)*	*1.254 (97.5)*			*0.1726*	*Best Fit*
2nd Order	3.132 (24.4)	1.223 (20.7)	0.00316 (0.5*)		0.1751	
3rd Order	3.035 (13.7)	1.316 (7.2)	-0.01898 (0.5*)	0.001476 (0.5*)	0.1777	

Polynomial fit analysis verified linearity of the Q-Pad Test System. The 2nd and 3rd order polynomials were determined to be "statistically equivalent to zero" making the best fit polynomial a linear function. The linearity of the Q-Pad Test System has been established from 4.4 to 14.5 %HbA1c. This range along with the totality of device performance supports a claimed measuring range (AMR) of the Q-Pad Test System of 4.0 to 15.0%.

Interfering Substances

Interference was assessed using methodologies described in CLSI EP07-Ed3. Studies were conducted to assess the Q-Pad Test System's performance in the presence of common exogenous and endogenous substances known or suspected to interfere with HbA1c measurements. Forty (40) substances were evaluated, each tested at four HbA1c levels. CLSI EP37 and similar references were used to determine the test concentrations for exogenous and endogenous substances. Test concentrations for bodily fluids were determined empirically using the analyzer. Topical products were tested by simulating normal use.

Significant interference was defined as a >10% bias between a spiked and an unspiked sample. The list of the substances tested is shown in Table 10, no incidence of interference was detected with any substance

Table 10. List of substances evaluated for interference and the highest concentrations tested with no measured interference (when applicable)

Endogenous and Exogenous Substances Tested	**Test Concentration**	**Topical Products Tested**
Acetaminophen	20.0 mg/dL	Lube Life Water-Based Personal Lubricant
Acetylsalicylic Acid	65.0 mg/dL	Good Clean Love Restore Moisturizing Vaginal Gel
Azo-Standard	0.0195 mg/dL	Replens Long Lasting Vaginal Moisturizer
Clindamycin	5.10 mg/dL	Bonafide Revaree Vaginal Moisturizer
Conjugated Bilirubin	40 mg/dL	Medicine Mama's Apothecary Vulva Balm
Glyburide	0.2 mg/dL	VCF Contraceptive Gel
Ibuprofen	50.0 mg/dL	Monistat 3 Yeast Infection Treatment
L-Ascorbic Acid	5.25 mg/dL	Monistat 1 Yeast Infection Treatment
Liraglutide	0.0168 mg/dL	Clotrimazole 3 Day Antifungal Cream
Metformin	4.0 mg/dL	Monistat Anti-itch Relief Cream
Metronidazole	12.3 mg/dL	Vagisil Maximum Strength Feminine Anti-Itch Cream
Rheumatoid Factor	600 IU/mL	Summer’s Eve Freshening Spray
Semen	25%*	Summer’s Eve Refresher Mist, Feminine Spray
Sitagliptin	0.115 mg/dL	Summer’s Eve Island Splash Body Powder
Sweat	50%*	Monistat Chafing Relief Powder Gel
Tinidazole	15.3 mg/dL	BORASOL Powder
Triglyceride-rich Lipoproteins	1640 mg/mL	Summer's Eve Feminine Wipes
Unconjugated Bilirubin	40 mg/dL	Vagisil Anti-Itch Medicated Feminine Intimate Wipes
Urine	40%*	Summer's Eve Douche Island Splash
Vaginal Fluid	50%*	Summer's Eve Vinegar & Water Douche

*highest test concentration that resulted in valid results for all four HbA1c levels.

Hemoglobin variants

Interference from Hemoglobin Variants, sourced from a NGSP reference laboratory, was evaluated following CLSI EP07-Ed3. Hemoglobin C, -D, -E, -F, and -S were tested at three HbA1c levels each. Samples were dosed onto a Q-strip, dried and run according to standard laboratory procedures. Measured values were compared to reference %HbA1c values supplied by NGSP. Significant interference was defined as a bias of >10% from the reference value.

No interference was detected for hemoglobin variants C, -D, -E, and -S. For Hemoglobin variant F, with variant concentration above 10%, interference was observed. The sponsor will include the following limitation in the product package insert, listed in the warnings and limitations section:

*"*This device has significant negative interference with fetal hemoglobin (HbF). HbA1c results are invalid for patients with abnormal amounts of HbF including those with known Hereditary Persistence of Fetal Hemoglobin.".

Traceability

The Q-Pad Test System is certified with the National Glycohemoglobin Standardization Program (NGSP). See NGSP website for current certification at http://www.ngsp.org. The Q-Pad A1c Test is traceable to IFCC reference calibrators.

Specimen Stability with Simulated Shipping

A sample stability with simulated shipping study, based on CLSI EP-25A, was performed on Q-Pad Kit collected menstrual blood samples. Eight (8) participants with known A1c levels, spanning the range of the assay used the Q-Pad Kit. Samples were exposed to 13 days of simulated summer/spring and winter temperature profiles. A reference measurement was taken at T0 and then at the following time points: Day-6, Day-10, Day-14, Day-28, and Day-31. At each time point, samples were punched once and run in triplicate. The acceptance criteria for each time point was <10% deviation from T0.

All measured values were within this acceptable range. In addition, no significant drift was observed, meaning none of the 95% confidence intervals of the regression lines crossed the TEa bounds. Based on these results, the Q-Pad Test System will have a claimed sample stability period of 28 days.

Shelf-Life

An Accelerated Shelf-life study was performed to establish initial shelf stability for the Q-Pad Kit. Q-Pad Kits were stored at constant elevated temperature (55^0C, 50%RH) for up to 3 simulated years (120 days). After aging, the kits were subjected to 7 days in an environmental chamber (Desert, Tropical, Frozen, and Room Conditions). Performance was evaluated using four HbA1c levels of bio-banked blood samples. A

set of Q-Pad Kits was run at the following time-points: 0 years, 1 year, 2 year, 3 year, and 3 year + 1 month, where a year corresponds to 40 days in the environmental chamber. HbA1c results from aged kits were compared to the reference value captured at the initiation of the study.

All measured values were within the acceptable range (<10% bias from reference). Based on the initial accelerated study results, Q-Pad Kits will be labeled with a 3 year shelf life. The outer pouch will include symbology to represent acceptable storage conditions as room temperature (15-30 ^{0}C). A real-time study is running concurrently to verify the results from the accelerated study.

An Open Pouch Shelf-Life study was performed to test the stability of a Q-Pad Kit after the main packaging is opened. Q-Pad kits were first subjected to 7 days in an environmental chamber (Desert, Tropical, Frozen, and Room Conditions). After stressing, the Q-Pad Kits were opened and then stored at room temperature for up to 67 days. Performance was evaluated using four HbA1c levels of bio-banked blood samples. A set of Q-Pad Kits was run at the following time-points: Day-0, Day-15, Day-30, Day-60, and Day-67. HbA1c results from aged kits were compared to the reference value captured at the initiation of the study.

All measured values were within the acceptable range (<10% bias from reference . The Open Pouch study adequately mitigates the risk that a kit opened but not used immediately would result in an inaccurate result.

Reference Interval

A reference interval study was performed according to CLSI EP28-A3c. Samples from 128 healthy participants were collected to establish a reference range for the Q-Pad Test System and to verify its equivalence to the The National Academy of Clinical Biochemistry (NACB) recommended HbA1c reference range of 4.0 to 6.0 %HbA1c.

All participant results were inside the expected reference range. The samples had a mean of 5.17 %HbA1c and a central 95% interval of 4.54% to 5.77%. The standard deviation of the dataset was 0.33%, and the CV was 6.34%. These results verify that the calculated reference interval for Q-Pad collected menstrual DBS samples falls within the standardized range recommended by NACB. Therefore, it is claimed that the reference interval for samples collected from healthy individuals using the Q-Pad Test System have a reference interval of 4.0% - 6.0%, equivalent to the range accepted for whole blood.

Clinical Studies

Method Comparison

A clinical validation study was performed to test the performance of the Q-Pad Test System. The study design followed CLSI EP09-A2 and CLSI EP21-A guidelines. IRB approval was obtained for participant enrollment and 396 specimens from 198 participants were utilized in the study. Samples were collected

using the Q-Pad kit according to the Instructions for Use (IFU) and were returned to the laboratory using USPS First-class Return Service. A venous blood draw was performed by a phlebotomist to provide the reference sample. Both samples were received and processed at Qvin Labs (CLIA certified clinical laboratory) using the Beckman Coulter Hemoglobin A1c Test on an AU480 chemistry analyzer.

The acceptance criteria for the comparative linear regression was a slope between 0.93 and 1.07 with a confidence interval that includes 1, an intercept between -0.7 and 0.7 whose confidence interval includes 0, and an R^2 of >0.95.

Participant HbA1c values ranged from 4.6% to 14.2%. 99% of participants successfully collected a sample. Linear regression analysis was performed to compare the results from the Q-Pad to the venous blood reference method using Passing-Bablok analysis, see Table 11.

Table 11. Summary of the clinical validation data

Method	Slope	95% CI	y-Intercept	95% CI
Passing-Bablok	1.003	0.987 - 1.02	-0.046	-0.170 - 0.067

99% of study subjects successfully collected and returned samples to the laboratory for analysis verifying the effectiveness of the Instructions for Use. The comparative methods exhibited strong correlation. No samples were outside of the stated total allowable error of 6%. The overall linear regression showed a slope of 1.003 (95% CI 0.987, 1.020), intercept of -0.0461 (95% CI -0.170, 0.0669) and R^2 of 0.99. The study met all acceptance criteria and demonstrated that the clinical performance of the Q-pad Test system is equivalent to the reference method using venous blood.

Usability Study

A dedicated usability study was conducted following the FDA Human Factors guideline. 40 naïve participants, who were self-reported diabetics, received the Q-Pad kit. Users followed the provided Instructions for Use to collect their sample and returned it to Qvin Labs via USPS First-Class Return Service. Each participant provided answers to a questionnaire regarding the use of the Q-Pad kit, the Qvin app and the mock results provided to them. The usability study showed that all 40 women were able to follow the Instruction for Use for the Q-Pad Kit, with 97.5% successfully collecting a sample that led to a valid HbA1c result.

Flex Studies

Elution Stability

The purpose of this study was to verify the stability of eluted menstrual blood samples collected using the Q-Pad Kit for up to 4 hours after extraction. Samples from four (4) participants were used. Samples were

extracted, aliquoted, and run immediately on the Beckman AU480. Additional aliquots were run at the following time points after extraction: 1, 1.5, 2, 3, and 4 hours. All samples were run in triplicate and the results from each timepoint were compared to the initial timepoint for each sample. Acceptance criteria was <10% bias between the measured time point and the initial measurement immediately after extraction.

For all time points and HbA1c levels, the maximum bias was 3.37%. The elution stability study verified the stability of the eluted sample for up to 4 hours.

Conclusion Drawn

Based on the comparison of technological features and intended use, and as a result of the non-clinical and clinical performance testing completed on Qurasense's Q-Pad Test System, the proposed device devices does not raise new questions of safety and effectiveness and supports the conclusion that the proposed device is substantially equivalent to the predicate device. The results of the non-clinical and clinical testing demonstrate the device is as safe, as effective and performs as well as or better than the predicate device.