510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K231465

B Applicant

Qurasense

C Proprietary and Established Names

Q-Pad Test System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCP	Class II	21 CFR 864.7470 - Glycosylated Hemoglobin Assay	HE - Hematology
QZG	Class II	21 CFR 862.1675 - Menstrual blood collection device	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Glycosylated Hemoglobin (HbA1c) with a menstrual blood collection device

C Type of Test:

Quantitative turbidimetric inhibition immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

- OTC – Over The Counter
- For in vitro diagnostic use only
- This test is not to be used to diagnose or screen for diabetes
- Should not be used in monitoring daily glucose control or to replace daily home testing of urine and blood glucose levels
- Should not be used for anlalyzing samples from patients with conditions causing shrotened red blood cell survival, such as hemolytic diseases, pregnancy, and significant acute or chronic blood loss
- Never adjust your medications or insulin on the basis of your A1c results alone

D Special Instrument Requirements:

Beckman Coulter AU480 at the designated single laboratory (Qvin Labs)

IV Device/System Characteristics:

A Device Description:

The Q-Pad Test System is comprised of the Q-Pad Kit and the Q-Pad A1c Test. The Qvin Q-Pad (Q-Pad) is an unscented menstrual pad which has an embedded dried blood spot collection device (DBS Collection Strip) designed to collect menstrual blood to enable subsequent HbA1c testing at the CLIA-certified Qvin Labs.

The Q-Pad Kit includes two Q-Pad sample collection devices with integrated DBS Collection Strips, a return sample container, a patient information card, a stamped mailing pouch, a package

insert, and instructions needed to collect, package, and mail the DBS Collection Strips to Qvin Labs for HbA1c testing using the Q-Pad A1c Test.

Once the DBS Collection Strips are received at Qvin Labs, the Q-Pad A1c Test is performed A sample is punched and eluted from a strip with the Beckman HbA1c Hemolyzing Reagent, then tested using FDA-cleared A1c reagents on the Beckman Coulter AU480 Chemistry Analyzer (k120199) according to the Q-Pad A1c Test laboratory standard operating procedure.

B Principle of Operation:

The Q-Pad Kit contains a menstrual pad that collects menstrual blood onto the DBS Collection Strip ("Q-Strip"), which can then be shipped to Qvin Labs for testing. The user removes the Q-Strip from the menstrual pad prior to shipping the sample. Once the dried blood sample is received by the designated laboratory, a trained professional performs the Q-Pad A1c Test by taking a circular punch from the strip, which is eluted with Beckman HbA1c Hemolyzing Reagent (k120199). Once eluted, the sample is assayed using FDA-cleared A1c reagents on the Beckman Coulter AU480 Chemistry analyzer.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Home Access A1c Test

B Predicate 510(k) Number(s):

K141944

C Comparison with Predicate(s):

Device & Predicate Device(s):	K231465	K141944
Device Trade Name	Q-Pad Test System	Home Access A1c Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	An in vitro diagnostic specimen collection and storage device intended for the collection of blood samples for subsequent analysis in a single designated laboratory. For the measurement of HbAlc for monitoring	Same

	the long-term control of blood sugar (glucose). This test is not to be used to diagnose or screen for diabetes.	
Location of Collection	Home	Same
Location of Analysis	Single Designated Laboratory	Same
General Device Characteristic Differences		
Sample Matrix	Menstrual blood collected in a menstrual pad during a woman's period	Capillary blood collected from the fingertip
Distribution	OTC	Prescription and OTC

VI Standards/Guidance Documents Referenced:

ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices

ISO 10993-1:2018 – Biological Evaluation of Medical Devices-Part 1: Evaluation and testing within a risk management process

ISO10993-3:2014 – Biological Evaluation of Medical Devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

ISO10993-5:2009 – Biological Evaluation of Medical Devices-Part 5: Test for in vitro cytotoxicity

ISO10993-10:2010 – Biological Evaluation of Medical Devices-Part 10: Test for Irritation and Skin Sensitization

CLSI-EP05-A3 (2014) – Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition

CLSI-EP07Ed3 (2018) – Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition

CLSI-EP37 – Supplemental Tables for Interference Testing in Clinical Chemistry

CLSI-EP28-A3C – Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory – Third Edition

CLSI-EP35 – Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures

ASTM D4332 (2022) – Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff (2/3/2016)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The sponsor provided multiple analyses to support the substantial equivalence of their device. The results from the following studies (except precision/reproducibility and method comparison) each reflect an assessment of 2-5 aliquots of a single eluent from the test strip. The sponsor also provided additional assessments that only included a single result from each test strip as per the Q-Pad A1c Test's instructions for use.

Menstrual Blood:

Precision was evaluated by testing menstrual blood samples obtained from 3 subjects with low, medium, and high HbA1c levels. Samples were collected per the Q-Pad Test System's instructions for use, following which samples were punched, extracted, and measured on the Beckman Coulter AU480 Chemistry analyzer at the designated laboratory according to the Q-Pad A1c Test instructions for use. Samples were run by one operator in duplicate for 5 days and 2 runs per day on one Beckman AU480 analyzer for a total of 60 measurements per sample. One Q-Pad Kit lot and one reagent lot was used. Results are shown below:

Sample	N	Mean %HbA1c	Repeatability (within-run)		Repeatability (within-day)		Total Within-Lab	
			SD	%CV	SD	%CV	SD	%CV
Low	60	5.28%	0.07	1.33	0.11	2.01	0.19	3.59
Medium	60	7.63%	0.10	1.32	0.11	1.43	0.16	2.15
High	60	12.35%	0.09	0.72	0.14	1.11	0.20	1.60

Venous Blood:

The sponsor provided a precision study using venous blood, a validated surrogate for the intended use sample, that measured the imprecision of patient samples and operator-to-operator variability over a 20-day time period.

The sponsor additionally provided data per CLSI EP35 to support that venous blood samples did not behave differently from menstrual blood samples.

Inter-strip and Intra-Strip Precision:

Inter-strip and intra-strip precision were each evaluated separately by testing menstrual blood samples obtained from 9 subjects with varying HbA1c levels (3 subjects <6.5%, 3 subjects between 6.5-8.5%, and 3 subjects >8.5%). Two Q-Strips were tested per subject for the inter-strip study, and three punches from a single Q-Strip were tested per subject for the intra-strip study. The results were as follows:

A1c Level	Mean %HbA1c (within-strip)	Repeatability (within-strip)		Mean %HbA1c (between-strip)	Repeatability (between-strip)	
		SD*	%CV		SD	%CV
< 6.5%	5.20%	0.49	1.15	5.32%	0.31	0.44
6.5-8.5%	7.29%	1.01	1.75	7.10%	0.21	2.59
> 8.5%	10.11%	0.49	1.08	11.67%	0.39	0.44

Lot-to-Lot Precision

The sponsor evaluated lot-to-lot reproducibility of the Q-Pad Test System through the use of 3 Q-Pad lots in their method comparison study. Samples were collected by users at home and shipped to the designated laboratory where they were eluted and tested according to the Q-Pad A1c Test instructions for use. Results from this analysis demonstrate acceptable lot-to-lot performance.

2. Linearity:

A linearity study was conducted to evaluate the linear range of HbA1c measurements from the Q-Pad Test System. Menstrual blood samples collected onto Q-strips were collected at 2 levels, then eluted and mixed to obtain 9 levels: 4.37%, 5.64%, 6.91%, 8.18%, 9.45%, 10.72%, 11.99%, 13.26%, and 14.53% HbA1c. The samples were eluted and measured on the Beckman Coulter AU480 Chemistry analyzer at the designated laboratory according to the Q-Pad A1c Test instructions for use, and the results were compared to the expected values (previously measured values for high and low; calculated values based on dilution factor for all others). The expected values were plotted versus the observed values. The results using standard linear regression analysis were as follows:

$y = 0.987x - 0.0365$; $R^2 = 0.997$

The study supports the sponsor's claimed measuring range of 4.0-15.0%.

3. Analytical Specificity/Interference:

i.) Endogenous and exogenous substances:

Potential interference from endogenous and exogenous substances was evaluated using menstrual blood samples at four levels of HbA1c (< 5.5%, 5.5-7.0%, 7.1-9.5%, and ≥9.5%). Menstrual blood samples were spiked with potential interferents. After drying, each sample and un-spiked controls were resuspended from the Q-strips, and %HbA1c was measured on the Beckman Coulter AU480 Chemistry Analyzer at the designated laboratory according to the Q-Pad A1c Test instructions for use. Results from the spiked test samples were compared to the results from the control samples. Significant interference was defined by the sponsor as greater than ± 10% difference between test and control results. The highest concentrations at which no significant interference was observed are summarized below:

Substances	Highest Concentration Without Significant Interference
Acetaminophen	20 mg/mL
Acetylsalicylic Acid	65 mg/dL
Azo-Standard Phenazopyridine HCL	0.0195 mg/dL
Bilirubin, conjugated	40 mg/dL
Bilirubin, unconjugated	40 mg/dL
Clindamycin	5.1 mg/dL
Glyburide	0.2 mg/dL
Ibuprofen	50 mg/dL
Liraglutide	0.0168 mg/dL
L-Ascorbic Acid	5.25 mg/dL
Metformin	4 mg/dL
Metronidazole	12.3 mg/dL
Rheumatoid Factor	600 IU/mL
Sitagliptin	0.115 mg/dL
Tinidazole	15.3 mg/dL
Triglyceride-rich lipoproteins	1640 mg/dL

ii.) Bodily fluids:

Potential interference from bodily fluids was assessed using the same protocol and acceptance criteria as described above for the endogenous and exogenous substance evaluations. Urine (at pH 5.45 and pH 7.5 and urine from people with Type-I and Type-II diabetes), semen, sweat, and vaginal fluid were applied to the Q-Pad in various amounts (up to 75%) relative to the amount of menstrual blood (as volume/volume percentage). Results demonstrated no significant interference of bodily fluids at amounts expected when samples are collected per the device's instructions for use; at higher bodily fluid concentrations, the Beckman Coulter AU480 Chemistry Analyzer identified the sample as unreadable, and no result was returned.

Samples contaminated with feces or excessive urine are visually recognizable as such, and the Q-Pad A1c Test includes instructions for laboratory operators to identify and reject these samples. Additionally, the labeling advises patients to identify and reject their own samples if they may be saturated with urine.

iii.) Topically applied substances:

Potential interference from substances topically applied to the vaginal area was assessed using the same protocol and acceptance criteria as described above for the endogenous and exogenous substance evaluations. Twenty potential interferents were chosen based on the most commonly used topical products, including a variety of active ingredients, and were evaluated by applying the amount recommended for use in the respective product instructions to the Q-Pad after the application of menstrual blood: vaginal lubricant, vaginal moisturizer, spermicide gel, yeast infection treatment, anti-itch cream, deodorant spray, feminine powder, feminine wipes, and douche.

No significant interference was observed from any of the products evaluated.

Additionally, the labeling for the home user contains the following statement:

> *Use of any products such as creams, lubricants, moisturizers, wipes, or deodorants, in or on your vagina before or during the use of the Q-Pad may cause inaccurate results. Ensure your intimate area is clean before using the Q-Pad.*

iv.) Hemoglobin variants

Potential interference from common hemoglobin variants (HbC, HbD, HbE, HbF, HbS) was evaluated using validated venous surrogate samples. Fifteen samples with varying levels of %HbA1c and hemoglobin variants were applied to Q-strips, eluted, and measured on the Beckman Coulter AU480 Chemistry Analyzer at the designated laboratory according to the Q-Pad A1c Test instructions for use. Test results were compared to known %HbA1c values obtained by a commercial reference laboratory. The sponsor defined significant interference as greater than ±10% difference between the candidate test result and the known result. The results of the study support the sponsor's claim that there is no significant interference from hemoglobin variants HbC, HbD, HbE, and HbS. Samples containing >10.9% HbF show a significant negative bias with the Q-Pad A1c Test. The following is a table of samples that were measured:

Hemoglobin Variant	% Content of Variant in Sample	Range in %HbA1c
HbC	31.5-34.4	5.5-7.6
HbD	39.0-39.7	5.1-6.5
HbE	23.0-25.5	5.4-9.1

Hemoglobin Variant	% Content of Variant in Sample	Range in %HbA1c
HbF	10.9-24.0	5.6-7.3
HbS	37.7-39.7	5.6-10.8

The labeling contains the following statement:

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.

4. Assay Reportable Range:

4.0-15.0% HbA1c. See section A.2 above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability

The Q-Pad A1c Test System has been certified by the National Glycohemoglobin Standardization Program (NGSP) and the Diabetes Control and Complications Trial (DCCT). The NGSP certification expires in one year. See NGSP website for current certification at http://www.ngsp.org. The Q-Pad A1c Test System is traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Method for Measurement of HbA1c.

Sample Stability

Several stability studies using menstrual samples were conducted to assess the performance of the Q-Pad Test System to collect and measure quality samples after undergoing simulated extreme shipping and distribution conditions (combinations of extreme cold, extreme heat, extreme humidities). Study protocols were reviewed and found to be acceptable. The study results support the sponsor's claim that the Q-Pad Test System performs as indicated when collected patient samples are shipped from the site of home collection, in the return sample container and provided mailing pouch, to the designated laboratory following the provided instructions.

Q-Pad Stability

Q-Pad stability was assessed using accelerated and real-time stability studies. Stability protocols and acceptance criteria were reviewed and found acceptable. The Q-Pad Kit labeling includes claims that the Q-Pad is stable for up to 60 days once the pouch is opened and until the expiration date printed on the packaging when unopened kits are stored between 59-86°F.

Elution Stability

Stability of eluted menstrual blood samples was confirmed by extracting, aliquoting, and running samples on the Beckman Coulter AU480 Chemistry Analyzer up to 4 hours after extraction. Laboratory stability protocols and acceptance criteria were reviewed and found acceptable.

6. Detection Limit:

The limit of detection for the Q-Pad A1c Test is based on the Beckman Coulter HbA1c reagents on the Beckman Coulter AU480 Chemistry Analyzer (k120199).

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted according to the instructions for use for the Q-Pad Test System. One hundred and ninety-eight (198) patients self-collected menstrual samples (4.6-14.2% HbA1c) at home using one of three lots of the Q-Pad. Samples were shipped per the instructions for use, then measured on the Beckman Coulter AU480 Chemistry Analyzer (k120199) at the designated laboratory. HbA1c results obtained with menstrual blood were compared to results from matched venous blood samples using the same Beckman Coulter HbA1c reagents. All samples were tested in singlicate.

Study enrollment was as follows:

%HbA1c Interval	Total %
< 5.5%	21.7%
5.5-7.0%	29.8%
7.0-8.5%	21.7%
8.5-11.0%	15.2%
> 11.0%	11.6%
All	100.0%

Passing-Bablok regression results are shown below:

$y = 1.003x – 0.0461$, $R^2 = 0.99$

Usability:

A usability study was conducted in which patients were asked to complete a usability questionnaire regarding the ease of understanding instructions for use when collecting and

shipping a sample. From the sponsor's analysis of the questionnaire responses, the patients were overall satisfied with the usability of the device.

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor performed a reference range study according to CLSI EP28-A3c in which 128 healthy participants self-collected menstrual samples according to the Q-Pad Kit instructions for use demonstrating a reference interval of 4.0%-6.0% HbA1c.

The sponsor includes the following in the labeling:
In 2023, the American Diabetes Association (ADA) recommended a reasonable A1c goal for many non-pregnant adults is < 7% (53 mmol/mol) without significant hypoglycemia. On the basis of health care professional judgment and patient preference, achievement of lower A1c levels than the goal of 7% may be acceptable and even beneficial if it can be achieved safely without significant hypoglycemia or other adverse effects of treatment. Less stringent A1c goals (such as <8% [64 mmol/mol]) may be appropriate for patients with limited life expectancy or where the harms of treatment are greater than the benefits. Health care professionals should consider deintensification of therapy if appropriate to reduce the risk of hypoglycemia in patients with inappropriate stringent A1c targets.[1]

Reference: American Diabetes Association, Standards of Medical Care in Diabetes - 2023 (Volume 46, Supplement 1)

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.