Package Insert

Q-Pad Kit & A1c Test

QH6.1.0

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.

Performance data

Matrix Equivalency

A CLSI EP35 based study was conducted to assess sample matrix equivalency between venous blood and menstrual blood collected on the Q-Pad. The linear regression resulted in a slope of 0.969 (95% CI 0.944, 0.994), an intercept of 0.181 (95% CI -0.017, 0.380) and a R^2 of 0.997. The systematic difference between specimens at the 6.5% predetermined medical decision point (MDP) was 0.3% and the 95% confidence interval was 6.42 to 6.54.

Precision Studies

Precision studies were performed according to CLSIEP06-A3. Three participants with a low, mid and high HbA1c level collected samples using the Q-Pad Kit according to the IFU. Samples were tested in duplicate, two times a day, over five days (N = 20 per level). Results are shown in Table 1.

Table 1: Menstrual Blood Precision

		Repeatability (within run)	Repeatability (within day)	Between day	Total
Sample	Mean %HbA1c	%CV (95%CI)	%CV (95%CI)	%CV (95%CI)	%CV
Low	5.28%	1.33 (0.41, 2.24)	2.01 (0.87, 3.15)	3.21 (1.59, 4.82)	3.59
Elevated	7.63%	1.32 (0.76, 1.87)	1.43 (0.97, 1.89)	1.83 (1.18, 2.48)	2.15
High	12.35%	0.72 (0.08, 1.36)	1.11 (0.40, 1.75)	1.22 (0.32, 2.12)	1.60

Intra-strip and inter-strip studies measured punch-to-punch and between strip variability, respectively. Three participants were used for each study. Results are shown in Table 2.

Table 2: Intra- and Inter-strip

Sample	Intra-Strip Precision Average %CV (95% CI)	Inter-Strip Precision Average %CV (95% CI)
Low A1c	1.15 (0.00, 2.36)	0.44 (0.00, 1.22)
Mid A1c	1.75 (0.00, 4.26)	2.59 (2.06, 3.11)
High A1c	1.08 (0.00, 2.30)	0.44 (0.00, 1.41)

Additional studies were performed to evaluate reagent, operator, and lot-to-lot precision. Lot-to-lot analysis was incorporated into the method comparison and shelf-life studies. Table 3 summarizes reagent and operator-to-operator precision. Lot-to-Lot data is displayed in Table 4 and 5.

Table 3: Reagent and Operator

		Between HbA1c reagent lots	Between hemolysis reagent lots	Between Operators
Sample	Mean %HbA1c	%CV (95%CI)	%CV (95%CI)	%CV (95%CI)
Low	5.2	1.26 (1.10, 1.43)	0.20 (0.18, 0.23)	1.88 (1.85, 1.92)
Elevated	6.7	1.24 (1.03, 1.44)	0.57 (0.47, 0.66)	1.98 (1.94, 2.02)
High	8.3	1.20 (0.95, 1.45)	1.06 (0.84, 1.28)	1.96 (1.91, 2.02)
Very High	12.7	1.43 (0.97, 1.89)	0.79 (0.54, 1.04)	1.80 (1.72, 1.87)

Table 4: Lot-to-Lot Precision

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

Table 5: Passing-Bablok Lot-to-Lot Regression Comparisons

	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)

Linearity

A CLSI EP06-A based linearity study was performed on the Q-Pad Test System using known interval methodology. High and low menstrual DBS samples were extracted and serially diluted to create a nine-member panel. Polynomial fit analysis determined that the "best fit" line was linear. 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 4.0 to 15 %HbA1c

Specimen Stability

A CLSI EP-25A based sample stability with simulated shipping study was performed on Q-Pad Kit samples. Eight samples were exposed to 13 days of simulated summer/spring or winter temperature profiles followed by room temperature storage. Measurements were taken at day 0, 6, 10, 14, 28, and 31. All measured values were within the acceptable range (<10% deviation from day 0). Based on these results, the claimed sample stability period is 28 days.

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 substances known or suspected to interfere with HbA1c measurements. Forty substances were evaluated, each tested at four HbA1c levels. No incidence of interference was detected with any of the substances listed in Table 6. Hemoglobin variants -C, -D, -E, -S, and -F were also tested. Hemoglobin -F resulted in an interference at variant concentrations of >10%. No interference was detected for the other variants.

Reference Range

A reference interval study was performed according to CLSI EP28-A3c. Samples from 128 healthy participants were collected. 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%. Therefore, the reference interval for the Q-Pad Test System is 4.0% -6.0%, equivalent to the National Academy of Clinical Biochemistry's recommended range[1].

The recommended A1c goal for many nonpregnant 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 target[2].

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. 198 participants were included. 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. Results are presented in Table 7 and Figure 1.

Table 6: List of substances with highest concentrations tested with no measured interference

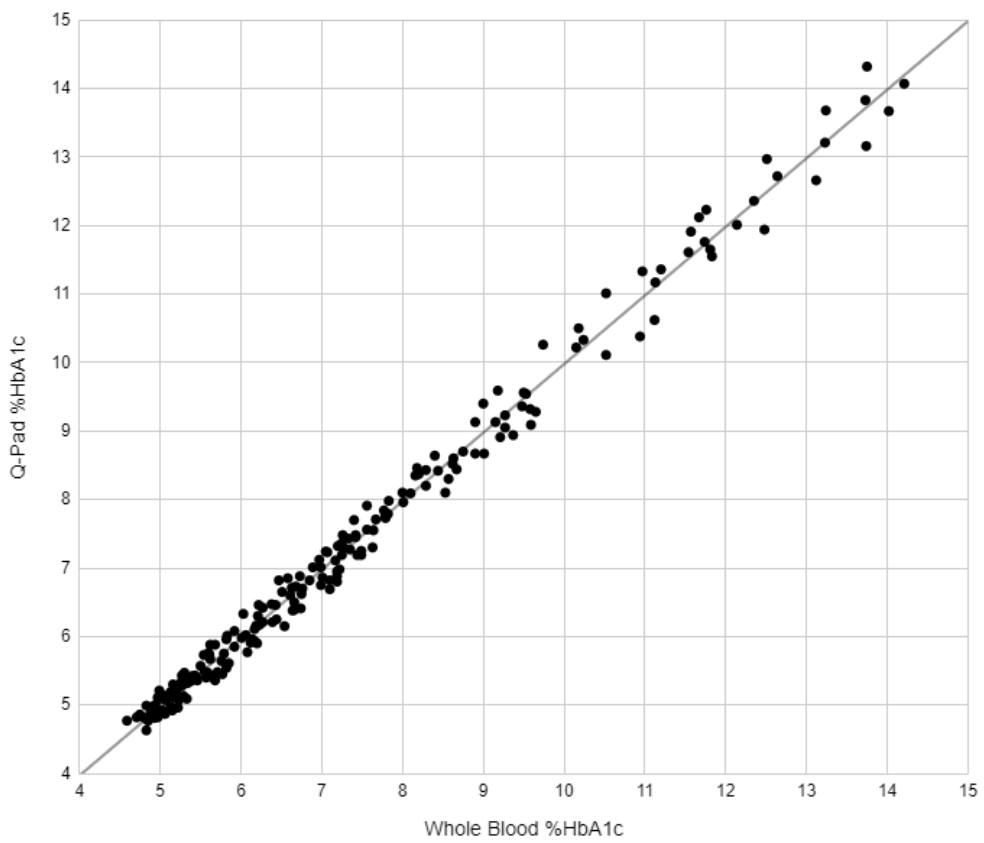
Endogenous and Exogenous Substances Tested	Test Concentration	Topical Products Tested
Acetaminophen	20.0 mg/dL	Lube Life Water-Based Personal Lubricant
Acetylsalicylic Acid	65.0 mg/dL	Good Clean Love Restore Moisturizing Vaginal Gel
Azo-Standard	0.0195 mg/dL	Replens Long Lasting Vaginal Moisturizer
Clindamycin	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 produced valid results for all four HbA1c levels.

Table 7: Method comparison study linear regression results.

Method	Slope	95% CI	y-Intercept	95% CI	R^2
Passing-Bablok	1.003	0.987 - 1.02	-0.046	-0.170 - 0.067	0.99

Figure 1: Graph of method comparison study data. Q-Pad %HbA1c vs. Whole blood %HbA1c



[1] Sacks DB et al.; National Academy of Clinical Biochemistry; Evidence-Based Laboratory Medicine Committee of the American Association for Clinical Chemistry. Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Diabetes Care. 2011 Jun;34(6):e61-99. doi: 10.2337/dc11-9998. PMID: 21617108; PMCID: PMC3114322.

[2] Nuha A. ElSayed et al.; on behalf of the American Diabetes Association, 6. Glycemic Targets: Standards of Care in Diabetes—2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S97–S110. https://doi.org/10.2337/dc23-S006

Warnings and Limitations

Wear the Q-Pad for max 8h
As with any other feminine hygiene product, it is not advised to wear your Q-Pad for longer than 8 hours.

Ship back within 72 hours
Please ship your samples back within 72 hours of starting Q-Pad 1.

Keep Storage Container in pouch
Use only the designated pouch and Sample Container to ship the product. Keep the Sample Container in the pouch at all times.

Avoid products on your vaginal area while using the Q-Pad
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

Engage your healthcare provider
Share the results with your doctor and discuss any changes to your treatment plan.

Elevated HbA1c
An A1c result that is greater than or equal to 6.5% may indicate an increased risk of diabetes.

Elevated Hemoglobin F
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.

Special instrument requirement
Beckman Coulter AU480 chemistry analyzer at Qvin Labs clinical laboratory.

Storage and Stability
Components in the Q-Pad Kit are stable until the expiration date printed on the packaging when stored at room temperature (15-30°C, 30-70% RH). Open kits are usable for up to 60 days when stored at room temperature (15-30°C, 30-70% RH).

Excessive urine
If you experienced excessive urination that is transferred to the Q-Pad or have urinated on the Q-Pad, consult customer service before submitting your Q-Pad to the laboratory.

Conditions affecting red blood cells
Q-Pads should not be used for analyzing samples from patients with conditions causing shortened red blood cell survival, such as hemolytic diseases, pregnancy, and significant acute or chronic blood loss.

Not a replacement
The Q-Pad is an important tool but should not be used in monitoring daily glucose control or to replace daily home testing of urine and blood glucose levels. Never adjust your medications or insulin on the basis of your A1c results alone.

For In-Vitro Diagnostic Use Only

Symbols Glossary


Biological Risks


Caution

In-Vitro Diagnostic Medical Device


Temperature Limitation

Catalogue Number


Do Not Reuse


Manufacturer

Qvin

If you have a question, customer service can be reached 9-5 PST M-F at **1-866-FOR-QVIN (1-866-367-7846)** or email **care@qvin.com** anytime. If you are having a medical emergency please contact your health care provider.

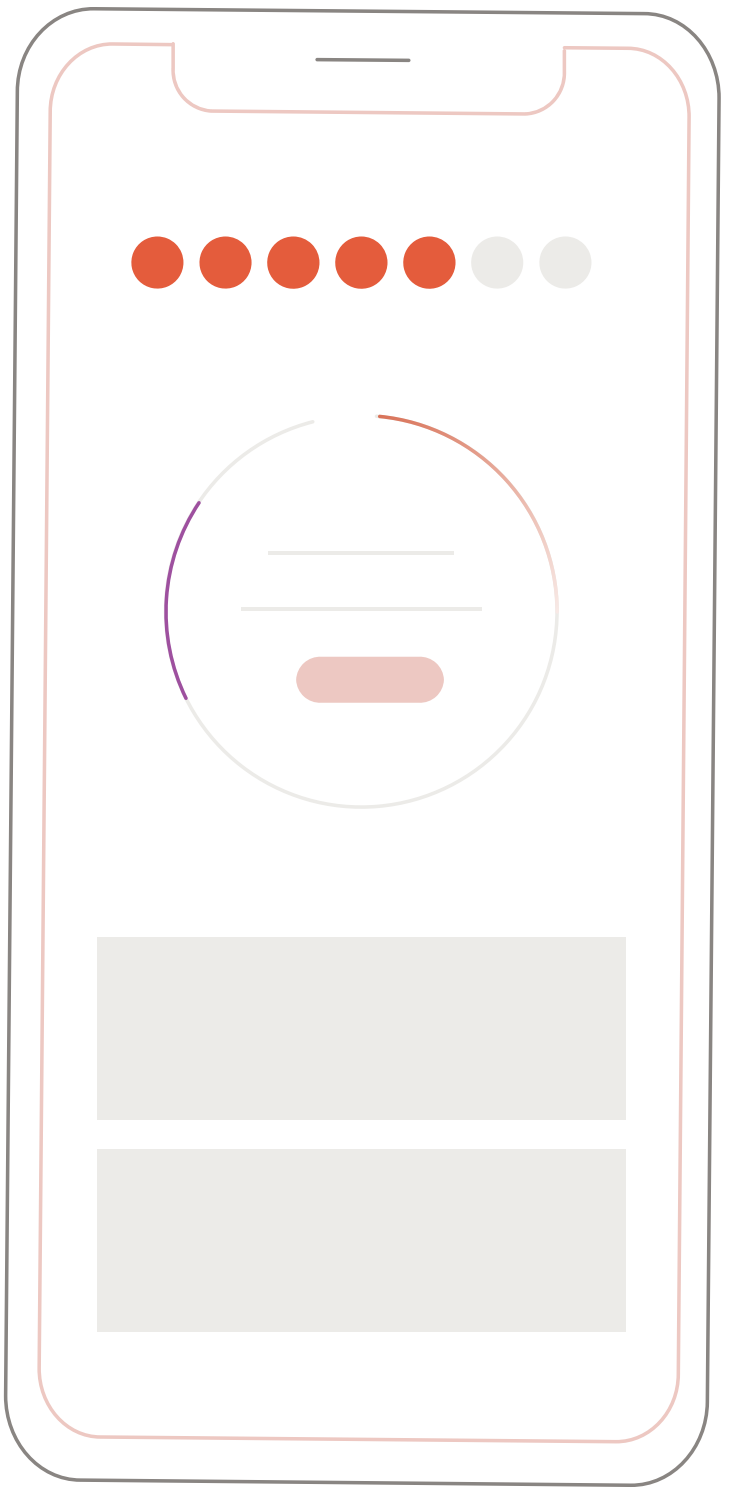
Qurasense Inc., 3517 Edison Way, Ste. D, Menlo Park, CA 94025, USA

Download the Qvin app and register your Q-Pad kit.

1

- Start by downloading the Qvin app--it's where you'll access your confidental health information when your test is finished.

- Register your Q-Pad kit with the ID on Q-Pad 1 before use.

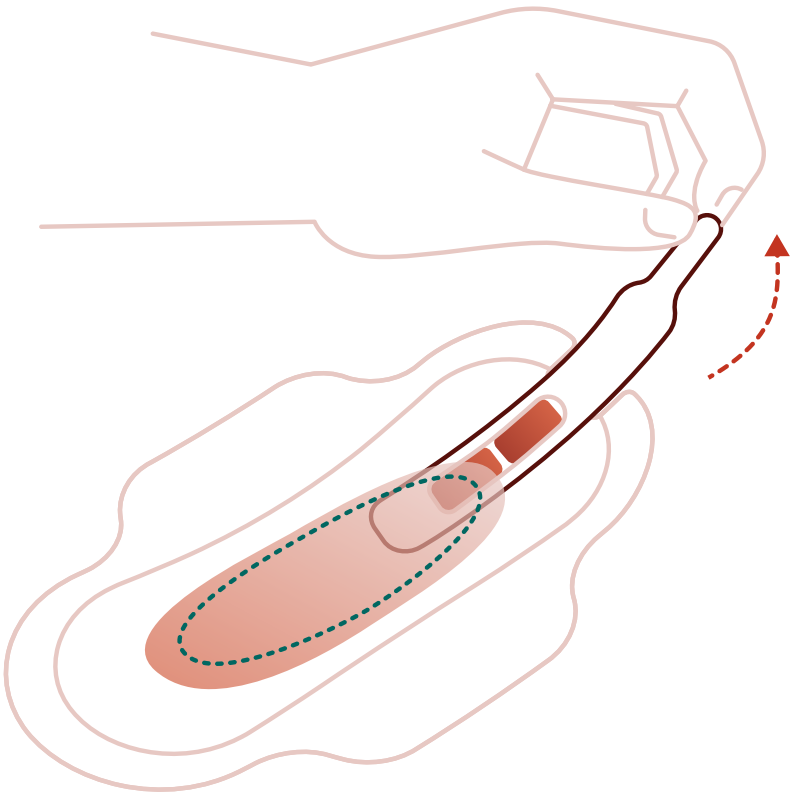


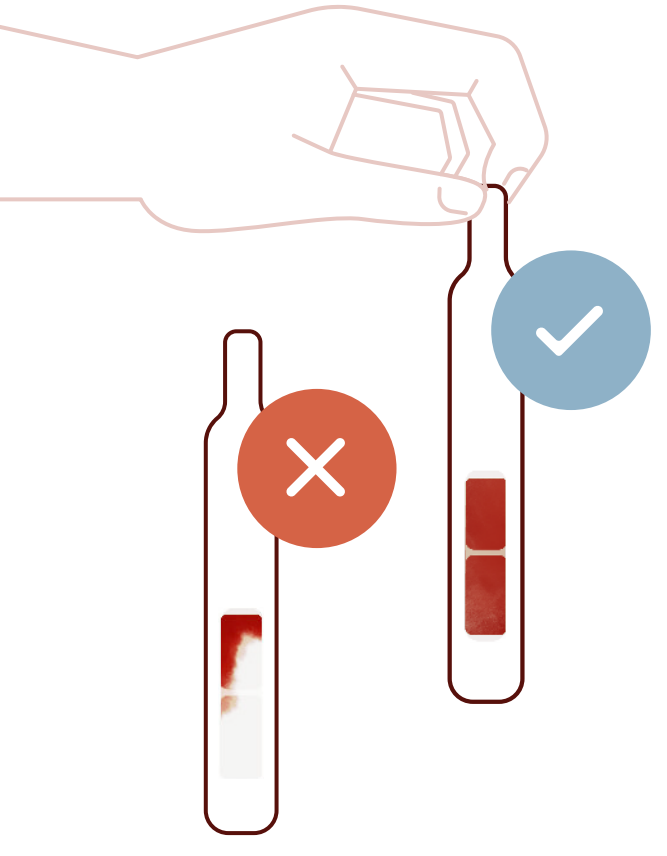
Scan or Tap QR to download the app

Use your Q-Pads on a heavy flow day.

2

- [ ] Before you use your Q-Pads, open the Qvin app and push “Use Q-Pad 1 now”.
- [ ] Start with Q-Pad 1 and wear it until the oval on the pad is covered.
- [ ] Pull the tab to remove the Q-Strip. It’s important that the Q-Strip is saturated. See illustrations below.
- [ ] Place the strip in the provided Storage Container immediately.
- [ ] Use Q-Pad 2 and repeat this process.

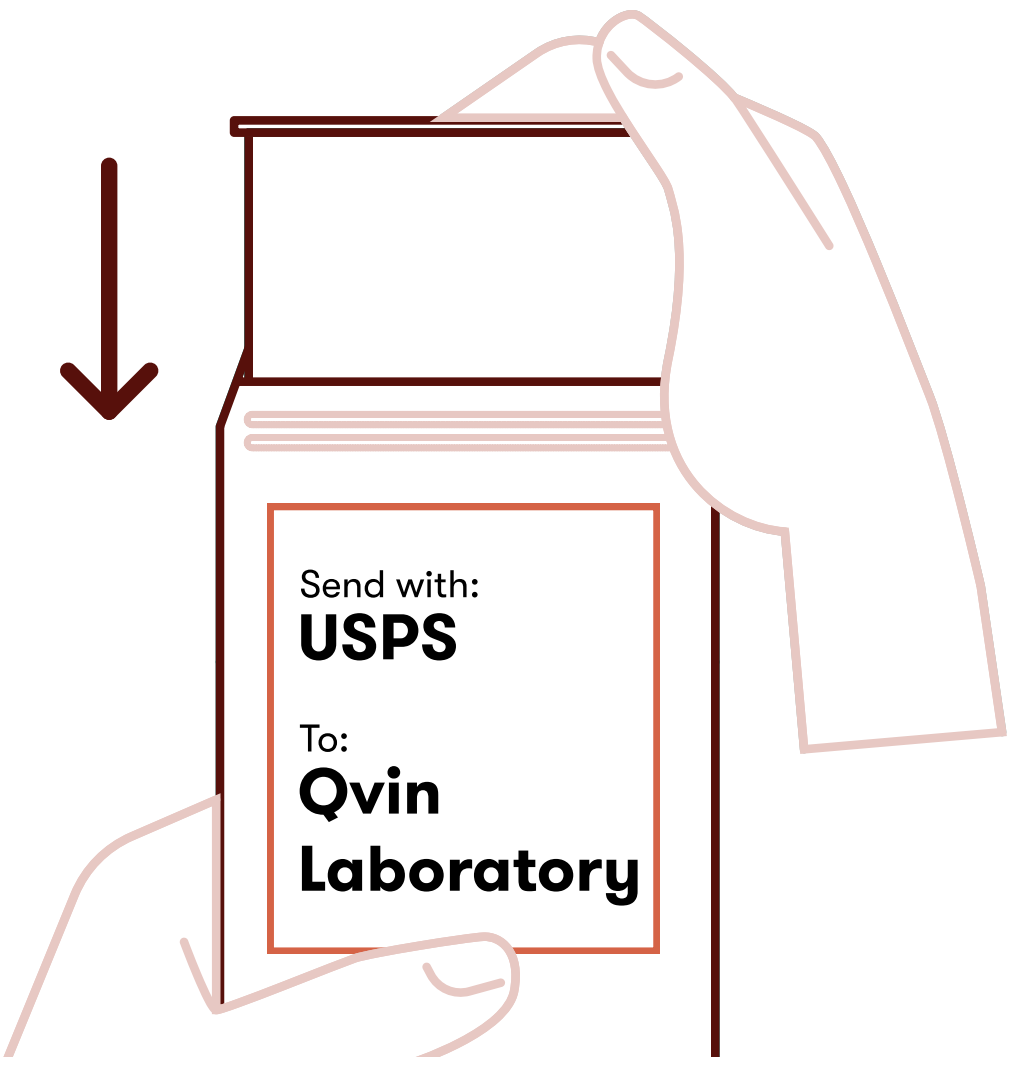




Mail the Sample Container via USPS within 72 hours.

3

- [ ] Put the Storage Container inside the Prepaid Return Mailer.
- [ ] Peel off the liner and seal the pouch.
- [ ] Drop it off at USPS within 72 hours.



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