

URINE KETONE TEST STRIPS

> Instruction Manual



BACKGROUND

Urine ketone test strips measure the presence and concentration of ketones in the urine. A urine ketone test can provide valuable insights into your health in various conditions, including diabetes, during pregnancy, fasting periods, or when following specific low-carbohydrate diets, such as the ketogenic diet.

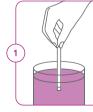
Ketone test from Diagnox offers a quick, accurate, and non-invasive way to check urine ketone levels. This is the same type of test healthcare professionals use to aid clinical decision-making. Unlike conventional strips in spin-top bottles that expire within a few days after they are opened, multiple resealable bags offer an extended shelf life, convenient handling, and easy storage so that you get a reliable test result every time.

INTENDED USE

Urine ketone test strips are intended for qualitative (presence or absence) and semiquantitative measurement (estimate of the quantity) of ketones excreted in the urine. This product is not intended for the management of diabetes.

DIRECTIONS FOR USE

Tear open the bag and remove one strip. Securely close the resealable bag. Hold the strip without touching the test pad. The test pad's color before performing the test has no clinical significance.



IMMERSE

Hold the strip in the urine stream or immerse it into the urine sample for 1 - 2 seconds (just enough to wet the test pad). If using a container, drag the edge of the strip against the container rim to remove excess urine.



WAIT

Remove excess urine by blotting the edge of the strip on a paper towel. Lay the strip flat with the test pad facing upwards. The result is ready to read 40 seconds after the test pad is wet.

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COMPARE

Compare the color of the test pad to the provided color key (printed on the bag) to find the dosest color match. Read results carefully in a good light. Do not read results after 2 minutes. The test pad color may continue to change. Any change in the color after 2 minutes is of no diagnostic significance.

COLOR CHART



A negative test for ketones will be indicated by a buff pink/peach color of the test pad. If your test result is negative, you may not observe any visible change in the color of the test pad after it has been moistened.

A positive test will result in a test pad that appears peach, pink, or purple/plum in color, as shown in the color chart above. The intensity of the test pad's color will correspond to the concentration of ketones in the urine.

Please be aware that your test pad may not produce an exact one-to-one match with the color key. In situations where the ketone concentration falls between two color levels, select the closest matching color.

WHAT DO THE RESULTS IMPLY?

Normally, measurable amounts of ketones do not appear in the urine. A negative result means that the concentration of acetoacetate ketone bodies in the urine sample was above trace levels (< 0.5 mmol/L).

A positive result for ketone in urine can mean different things to people with various health conditions/goals.

- When following a ketogenic diet, trace-to-moderate ketone levels are desirable to enter a state of nutritional ketosis to promote weight loss. In diabetic patients, a positive result can be a sign of insufficient insulin levels and increases the risk of diabetic ketoacidosis, which is a serious complication of diabetes.
- During pregnancy, ketones in urine can indicate gestational diabetes. They can also be a sign that you're not consuming enough calories and carbohydrates.
- Physiological stressful conditions such as vomiting, strenuous exercise, fasting, long gaps between meals, eating disorders, and alcohol abuse can also cause positive results.
- If ketone levels surge to dangerously high levels, it is referred to as ketoacidosis. Clinically relevant forms of ketoacidoses include diabetic ketoacidosis, alcoholic ketoacidosis, and starvation ketoacidosis, all requiring prompt medical intervention.



SCAN THIS QR CODE TO STEP UP YOUR KETO JOURNEY WITH KNOWLEDGE, CARE, AND EASE.

LIMITATIONS OF USE

- The test is semiquantitative (estimate of levels).
- The test reacts with acetoacetate ketone bodies in urine. It does not react with acetone or Beta-hydroxybutyrate ketones.
- Improperly timed readings can lead to false results.
- Substances that cause abnormal urine color, such as drugs containing azo dyes, nitrofurantoin, and riboflavin, may affect the readability.
- False-positive results may occur when the urine specimen is highly pigmented or when it contains large amounts of levodopa metabolites.
- Medications containing sulfhydryl groups may cause a false-positive or atypical color reaction.
- False positives may appear in some samples with high specific gravity (concentrated urine) and low pH.
- This product is not intended for the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. The product is not a substitute for professional medical advice, clinical diagnosis, or treatment.

STORAGE AND HANDLING

- Store at 36°F-86°F (2°C-30°C).
- Keep away from sunlight, heat, and moisture.
- Do not remove the desiccant from the bag.
- Securely seal the resealable bag after each use.
- Do not touch the test area of the strip.
- Once a resealable bag is torn open, use all strips in the bag within 60 days. Tests in unopened sealed bags can be used up until the expiration date.
- Discard any expired or discolored strips that may have deteriorated.













CARE TO KNOW

WHAT ARE KETONES?

Ketones are chemicals produced by our bodies that serve as an alternate energy source when glucose (the body's primary energy source) is scarce or not available. Everyone has them, but they are more prevalent in people who fast or consume a low-carbohydrate diet or individuals with chronic conditions like diabetes that inhibit the body's ability to produce sufficient insulin.

WHAT IS DIABETIC KETOACIDOSIS?

Diabetic ketoacidosis is a diabetes-related complication in which ketone and glucose concentrations in the blood get dangerously high due to a lack of insulin. It is a life-threatening condition that requires prompt medical attention, necessitating regular ketone monitoring.

WHAT IS (NUTRITIONAL) KETOSIS?

Nutritional ketosis is a diet-induced condition that occurs when your body produces a steady state of ketones, which implies that the body is burning stored/consumed fat for energy. It is desirable for individuals following a ketogenic lifestyle to achieve potential health benefits, including weight loss.

TARGET KETONE LEVELS

The normal level of ketones in the body is less than 0.6 mmol/L, which is indicated by a negative urine ketone test. Any level higher than this will trigger ketosis.

Light Nutritional Ketosis: A urine or blood ketone reading between 0.5 – 1 mmol/L (Trace to Small) suggests your body is in a light state of ketosis.

Optimum Nutritional Ketosis: A urine or blood ketone reading between 1 – 3 mmol/L (Small to Moderate) is a desirable range for optimum ketosis.

Please consult your healthcare provider or nutritionist to find a target ketosis level.

THE DIFFERENT TYPES OF KETONES

There are three types of ketone bodies.

Acetoacetate (AcAc): AcAc is the first type of ketone body produced by the liver when fat is metabolized. It is the primary form of ketone, and other ketone bodies are derived from it. Excess AcAc is excreted in the urine and is common during the early stages of ketosis. AcAc ketone bodies are commonly tested using a urine ketone test (such as this one).

Beta-hydroxybutyrate (BHB): BHB is formed from the reduction of AcAc ketones in the cells and is the most abundant form of ketone in the body. Both AcAc and BHB ketone bodies are energy-rich compounds that transport energy from the liver to other tissues. BHB can be measured using a capillary (finger-prick) blood test with an over-the-counter ketone meter or in the laboratory with a serum blood test (capillary and serum ketone levels may differ).

Acetone: Acetone is produced by AcAc ketone bodies and is a waste product that is exhaled during breathing. Acetone is responsible for the sweet odor on the breath of individuals in nutritional ketosis and ketoacidosis. Acetone measurement is performed using a ketone breath meter and is a measure of ketosis level.

WHAT IS THE DIFFERENCE BETWEEN URINE, BLOOD, AND BREATH TEST?

Urine Ketone Test: A urine ketone test is a simple, pain-free, and non-invasive way to check ketone levels. A standard urine ketone dipstick test can only check Acetoacetate (AcAc) ketone bodies, not BHB ketones.

Excess AcAc is excreted in the urine, indicating the body's ketosis level. Urine ketone testing reflects the average ketone levels (as compared to the instantaneous level with a blood test).

A urine ketone test necessitates a urine sample and reagent test strips. It is also the most cost-effective and readily available method to test ketone levels.

Due to their convenience and practicality, they are one of the most popular options for checking ketosis levels, especially at the start of a keto regimen, because ketones appear in the urine in excessively high concentrations before blood ketones are elevated.

Blood Ketone Test: A blood ketone test provides a direct and instantaneous measurement of ketone concentration in the bloodstream. A home blood ketone test only checks Beta-hydroxybutyrate (BHB) ketone bodies, not AcAc or acetone ketones.

A blood ketone test gives a snapshot of ketone concentration at the time the sample was collected. Since BHB concentration in the bloodstream fluctuates, a single measurement may not be sufficient to represent the complete/average ketone profile.

A home blood ketone test requires a digital meter, test strips, lancets, and a lancing device. It may be painful for some individuals since it requires a finger prick to extract blood. It is a preferred test, especially for people at risk of diabetic ketoacidosis. Precise meter calibration is crucial to ensure result accuracy.

Breath Ketone Test: A breath ketone test is a non-invasive, quick, and convenient way to check the exhaled acetone concentration. Breath meters only check for acetone ketone bodies (not AcAc or BHB).

Similar to a blood test, they provide a snapshot status of the body's ketone levels at the time of the test. Since acetone levels can vary throughout the day due to numerous factors, several measurements are essential to draw an accurate ketone profile.

A home breath ketone test requires an electronic meter to perform the test, which may be expensive. Meters are sensitive to calibration errors, and acetone sensors may need replacement for accurate functioning.

WHICH TESTING METHOD TO CHOOSE?

All three tests have their pros and cons. The test choice will depend on the type of measurement intended (instantaneous vs. average levels), the type of ketone body to test (ACAC, BHB, or Acetone), equipment, expense, and human factors (such as comfort level with a finger-prick, etc.).

While blood and urine tests are most common in medical practice, clinical evidence suggests complementary measurements from all three types of tests can offer comprehensive insights into your body.

The best test is the one which you will actually use. Avoid drawing diagnostic conclusions from a single test result. Your nutritionist/healthcare provider can help you identify the best test type for your specific health and wellness needs.

WILL MY RESULTS FROM THE URINE AND BLOOD TEST MATCH?

Since both tests measure two different types of ketone bodies, your results may not match. Also, a urine test gives you an average ketone profile, whereas a blood test gives you ketone concentration at the time of the test (which changes throughout the day).

HOW ACCURATE IS THIS TEST?

Urine ketone test strips by Diagnox offer clinical-grade accuracy. The analytical performance of the ketone reagent pad with urine controls in a multi-side study demonstrated a mean test accuracy of 95% (percentage exact match) when reading strips visually (n=180).

You can access the complete validation data by visiting *diagnox.health/product/ketonox*

ABOUT DIAGNOX

We believe that promoting and sharing knowledge is a form of care. With this mission, we make it easy for people to take charge of their own health.

Listen to your body and get to know yourself to own yourself.

Being the protagonist of your well-being is having information at the palm of your hand. With that in mind, we provide innovative health tests that provide accurate results along with simple-to-understand information and all the support needed for you to connect the dots and be aware of your health. After all, good decisions come from good information.

It is knowledge from the inside out that guides us to look after ourselves and others around us, raising awareness for better health for all.

Diagnox Care to Know. Know to Care.

QUESTIONS?

For questions, please contact us at: contact@diagnoxhealth.com Diagnox LLC, Plano, TX 75024 - USA

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