



Ketone Test Strips

Reagent Strips for Urinalysis

For Self-testing

HOW DOES THE TEST WORK?

Easy@Home Ketone Test Strips are for single use, at home self-testing. The ketone strips are intended as an aid to check for ketones in urine. The test is a firm plastic strip onto which Ketone (KET) test pads are attached. If the test is positive, the Ketone test pad produces a color change from beige to dark purple.

The ketone strips are intended for use by people with diabetes and/or people on low carbohydrate diets. This product is not intended for diabetes management.

Ketone (KET) test pad



Reagent	Read Time	Composition
Ketone (KET)	15 to 120 seconds	5% w/w Sodium nitroprusside; 95% w/w buffer

Please read all the information in this package insert before performing the test.

- For urine testing only. Do not use for blood testing.
- Do not use after the expiration date.
- Keep out of the reach of children.
- For in vitro diagnostic use. Not to be taken internally.
- The used strip should be discarded after testing. Do not reuse test strips.
- If ketones are present, please see a doctor to have your ketone levels tested.

WHAT MATERIALS ARE PROVIDED WITH THE TEST?

- Test strips
- Package Insert
- Color chart on pouch label

WHAT MATERIALS ARE NEEDED BUT ARE NOT PROVIDED WITH THE TEST?

- Timer or watch with a second hand
- Absorbent material (e.g. paper towel)
- Urine collection container (optional)

HOW DO I PERFORM THE TEST AND READ THE RESULTS?

Note: Any visual impairment, including but not limited to color blindness, will affect the user's ability to read the test results.

To perform a midstream test

1. Gently wash the genital area thoroughly with soap and water then rinse well prior to testing. Wash your hands.
2. Remove the strip from the pouch and use the strip as soon as possible.
3. Hold the end of the strip farthest away from the test pad(s) and begin urinating. After 1 or 2 seconds of passing urine, hold the strip downward with the test pad pointing into the urine stream for 1 - 2 seconds. Make sure the test pad is completely wet. **See Illustration 1.**
4. After removing the strip from your urine, immediately bring the edge of the strip into contact with an absorbent material (e.g. paper towel) to remove excess urine. **See Illustration 2.** Lay the strip with the test pad(s) facing upwards and begin timing.
5. You may read results starting at 15 seconds and for up to 2 minutes. Read results within 2 minutes. After 2 minutes, the results may not be accurate.

Compare the test pad to the color blocks on the pouch label. Make sure that you read the results in a well-lit area. Hold the strip close to the color blocks, and carefully match the pad to the color chart. **See Illustration 3.** Discard the strip after 2 minutes.



Illustration 1

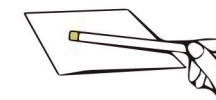


Illustration 2



Illustration 3

To perform testing on collected samples:

1. Wash your hands.
2. Urine specimen must be collected in clean and clear container and should be tested immediately.
3. Remove the strip from the pouch and use the strip as soon as possible.
4. Dip the test pad on the strip completely into the urine for 1-2 seconds and remove immediately. **See Illustration 4.** Run the edge of the strip against the rim of the urine container to remove excess urine. **See Illustration 5.**
5. You may read the result starting at 15 seconds and for up to 2 minutes. The results should be read within 2 minutes. After 2 minutes, the results may not be accurate. Compare the test pad to the color blocks on the pouch label. Make sure that you read the results in a well-lit area. Hold the strip close to the color blocks, and carefully match the pad to the color chart. **See Illustration 6.** Discard the strip after 2 minutes.

Note: Perform testing immediately after collecting urine sample.



Illustration 4



Illustration 5



Illustration 6

WHEN SHOULD I PERFORM THE TEST?

You should perform the test if you think you are likely to have higher than normal ketone levels in your urine. This can happen if you are on a low carbohydrate diet or if you are a diabetic.

In the body, carbohydrates are converted to glucose. Glucose is the body's main source of energy. Insulin is used to help process glucose in the blood to give the body energy. When blood glucose is not available for energy, the body will use fat stores to make ketones for energy. Ketones are molecules produced by the liver from fatty acids during periods of low food intake, carbohydrate restrictive diets, starvation, prolonged intense exercise, or in untreated type 1 diabetes mellitus.⁵ Excess ketones are discarded in urine.¹

- **For people on low carbohydrate diets** who do not have diabetes, low consumption of complex carbohydrates and sugars promotes the use of energy from fat rather than blood glucose as the primary source of energy for the body. When this occurs, the body produces ketones. This is called ketosis.¹ Ketosis may represent a health concern and you should contact your health care provider immediately if ketones are detected in your urine.
- **For people with diabetes**, a lack of sufficient insulin prevents the body from using blood glucose properly. Without enough glucose for energy, the body produces ketones from fat and muscle for energy.² This is called diabetic ketoacidosis (DKA). DKA is a significant health risk and you should contact your health care provider immediately if ketones are detected in your urine.

HOW DO I STORE THE TEST STRIPS?

- Store in a dry place at 36°F-86°F (2°C-30°C). Do not freeze. Keep out of direct sunlight.
- The strip should remain in the sealed pouch until use.
- Test strips are sensitive to prolonged exposure to moisture, heat, and light.
- Do not use if pouch is torn or damaged.
- Do not touch the test pad of the strip. Discard any discolored strips that may have deteriorated.

WHAT DO THE COLOR BLOCKS ON THE POUCH LABEL REPRESENT?

The color blocks on the pouch label are used to read the results by comparing the test pad color to the blocks on the chart. Match the color of the test pad to the closest color block on the color chart. The color blocks represent approximate concentration values of ketones in your urine. The color blocks from left (light color) to right (dark color) represent Negative (-), 5 mg/dL (+/-), 15 mg/dL (+), 40 mg/dL (++) and 80 mg/dL (+++) and 160 mg/dL (++++). Proper read time is important for best results.

WHAT DOES IT MEAN IF MY RESULT IS POSITIVE?

Normal urine will not have any ketones present. If your results are positive, you should immediately consult your health care provider. A positive ketone level in urine is called ketonuria. This can occur in the following instances:

- When a person is on a very low carbohydrate diet.
- When diabetes mellitus is out of control.
- As a result of fasting, dieting, starvation, eating disorders, high protein diets and isopropanol ingestion.
- Ketonuria may be noted in normal pregnancy.

Immediately consult your health care provider if ketones are detected in your urine.

WHAT DOES IT MEAN IF MY RESULT IS NEGATIVE?

A negative result means that ketones were not detected in the urine and the urine ketone level is normal.

WHAT SHOULD I DO IF I THINK I PERFORMED THE TEST INCORRECTLY?

If you think you performed the test incorrectly, you can:

- Check the expiration dates. If expiration date has passed, discard strips. Repeat test with strips from a new pouch.
- Check for discoloration of unused Test Pad. Discoloration may occur if pouch was not completely sealed. Repeat test with strips from a new pouch.
- If you have questions or concerns, call the 24/7 customer service for assistance at 1-855-822-6999.

DO ANY DRUGS OR MEDICATIONS AFFECT THE TEST?

- Urine that is especially dark or taking medications that contain certain sulfhydryl substances (for example, medications such as mesna, captopril, and penicillamine) that turn urine dark may lead to false positive results⁴ (indicate that ketones are present when in fact no ketones are present).
- Blood in urine can lead to false positive results.
- Some medications change the color of urine and make the result hard to read. These include Pyridium®, Azo Gantrisin®, Azo Gantano®, nitrofurantoin (Macrochantin®, Furadantin®) and riboflavin. These hide color development on the strip or can lead to false positive results.⁴

REFERENCES

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2. Diabetes - Urine Ketone Testing, Dept. of Nursing Services & Patient Care. Virtual Hospital. Retrieved 10 March 2004 from www.vh.org/adult/patient/internalmedicine/urineketonetesting.
3. Jacobs & DeMott. Laboratory Test Handbook
4. Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.
5. Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.
6. Koeslag, J.H.; Noakes, T.D.; Sloan, A.W. (1980). "Post-exercise ketosis". *Journal of Physiology*. 301: 79–90.

PRECAUTIONS

Keep out of the reach of children.
Store between 36°F-86°F (2°C-30°C)
Do not re-use.

Do not use test kit beyond expiry date.
Do not use the kit if the pouch is punctured or not well sealed.

If you have any questions, please call us toll-free at **1-855-822-6999(Monday-Friday 9:00 a.m.- 5:00 p.m Central Time)**. Our professional staff will be glad to assist you.

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