

TRUEplus® Urine Test Strips for Ketones

Instructions for Use

Summary: In the body, carbohydrates are converted to glucose. Glucose is the body's primary source of energy. Insulin is needed to help process glucose in blood to supply the body with energy. When blood glucose is not available for energy, the body will use fat stores to produce ketones for energy. Excess ketones are discarded in urine.¹

Intended Use: Intended to identify ketones in urine. This product is not for the management of diabetes.

For low carbohydrate dieters who are not diabetic, low intake of complex carbohydrates and sugars promotes use of ketones from fat stores rather than blood glucose as the primary source of energy for the body. When this occurs, the body produces a steady state of ketones (ketosis).¹

For diabetics, 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 (ketoacidosis), and blood glucose levels remain high. When blood glucose levels remain high, health risks increase.¹ This product is not for the management of diabetes.

WARNING!

If you have any of the following symptoms, contact your healthcare provider IMMEDIATELY, or go to the nearest emergency room of your local hospital.

Possible Symptoms of ketoacidosis include:

- Thirst or very dry mouth
- Frequent urination
- Constantly feeling tired
- Dry or flushed skin
- Nausea, vomiting, or abdominal pain
- Difficulty breathing
- Fruity odor on breath
- A hard time paying attention, or confusion

Product Description: TRUEplus Ketone Test Strips consist of a Test Pad mounted on a plastic strip. Test Pad changes color as it reacts with ketones in urine. Color is visually compared to color chart printed on test strip vial label. This color comparison is used to determine urine ketone levels ranging from negative to large.

WARNING!

Upon opening the test strip carton, examine the product for missing, damaged or broken parts. Ensure the test strip vial cap is securely closed. If the product is damaged or the vial cap is not closed, DO NOT use the test strips for testing; product may give inaccurate results. Contact Trividia Health Customer Care at 1-800-803-6025 for replacement and assistance.

Precautions

- TRUEplus Ketone Test Strips are for *in vitro* diagnostic use only.
DO NOT CONSUME.
- TRUEplus Ketone Test Strips are used for urine testing only.
DO NOT USE for blood testing.
- Do not transfer Test Strips from one vial to another.
Store Test Strips in original vial only.



How to Perform a Urine Ketone Test

1. Remove Test Strip from vial. Close vial immediately.
NOTE: *If opening vial for first time, write date opened on vial label.*
2. Check 'Use By' date (printed) and 'Opened' date (written) on vial. Do not use if either 'Use By' date has passed or if it is 5 months past 'Opened' date. Discard vial and test with new vial.
NOTE: *Use of Test Strips past expiration dates may cause incorrect results.*
3. Firmly hold end farthest away from Test Pad. Pass Test Pad through urine stream.
NOTE: *Urine may also be collected in a clean, dry container for testing. After collection, quickly dip Test Pad into urine. Drag long edge of Test Strip against rim of container to remove excess urine.*
4. At 15 seconds, match Test Pad to color chart on vial label. Ignore any color changes after 15 seconds.

NOTE: *Color Chart blocks give approximate ketone level; actual colors may be slightly darker or lighter than color shown on chart. If replacement Color Chart is needed, call for assistance.*

5. Discard used Test Strip in appropriate container.

Expected Results: Ketone results are read from Color Chart as negative (0 mg/dL) to large (approx. 160 mg/dL). Normal urine usually gives negative results. For diabetics, call your Doctor or Diabetes Healthcare Professional if result level is Moderate (approx. 40 mg/dL) to Large (approx. 160 mg/dL) to confirm your results.¹ This product is for the monitoring of ketones, not for the management of diabetes.

Unusual Test Results

1. Check 'Use By' date and 'Opened' date. If 'Use By' date has passed or it is 5 months past 'Opened' date, discard Strips and repeat test with Strips from a new vial.
2. Check for discoloration of unused Test Pad. Discoloration may occur if vial cap was not completely closed, or if vial was stored in extreme heat or cold. Repeat test with Strips from a new vial.
3. If your urine ketone result does not match the way you feel, please contact your healthcare provider to confirm your ketone level.

If you have questions or concerns, call Trividia Health Customer Care at 1-800-803-6025 Monday - Friday 8AM-8PM EST for assistance.

Storing Test Strips

- Test Strips must be kept in their original, capped, labeled vial. Contact with moisture may cause incorrect results. After removing Strip from vial, immediately recap vial.
- Store Test Strips in a dry place at room temperature below 86°F (30°C).
DO NOT REFRIGERATE OR FREEZE.
- Do not store vial in direct sunlight.

Limitations: Substances known to cause abnormal urine color, such as drugs containing azo dyes (i.e. Pyridium®, Azo Gantrisin®, Azo Gantonol®), nitrofurantoin (i.e. Macrodantin®, Furadantin®), and riboflavin, may affect the readability of the Test Pad. Strongly colored urine samples or those containing large amounts of levodopa metabolites may mask color of Test Pad and may cause negative result to appear as positive. Blood and compounds that contain a sulfhydryl group, such as MESNA (2-mercaptoethane-sulfonic acid), may cause false positive results.²

Test Principle: TRUEplus Ketone Test Strips are specific for acetoacetic acid (ketones). When urine is absorbed into Test Pad of Test Strip, any acetoacetic acid present reacts with nitroprusside to cause color change. Color produced by the reaction ranges from beige (negative, 0 mg/dL) to maroon (large, approx. 160 mg/dL). Each color block represents a ketone level. Because of urine and reading variability, ketone levels that fall between color blocks may give results for either color block.

Chemical Composition: 7.6% w/w sodium nitroprusside, 92.4% buffer and nonreactive ingredients.

Performance Characteristics: Urine ketone test results were compared using the TRUEplus Ketone Test Strips and urine ketone strips sold by a leading manufacturer. The study showed that there was 100% agreement for all samples tested.

50 TRUEplus Ketone Test Strips from multiple vials of three lots were tested using standards containing 0 mg/dL and 15 mg/dL acetoacetic acid. The strips showed that 100% tested negative using the 0 mg/dL standard and 100% tested positive (small to larger) using the 15 mg/dL standard.

TRUEplus Ketone Test Strips do not detect acetone or 2-hydroxybutyric acid.

References:

1. DKA (Ketoacidosis) & Ketones. American Diabetes Association.
<http://www.diabetes.org/living-with-diabetes/complications/ketoacidosis-dka.html>
2. G. Csako, CLINCHEM, 33/2, 289 (1987).