TRUEplus® Urine Test Strips for Ketones Instructions for Use

Intended Use: This product is intended to be used by people with diabetes and people on low-carb diets at home to check for the presence of ketones in urine. This product is NOT intended for the management of diabetes. This product is NOT intended for professional use or for near patient testing (point of care).

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]

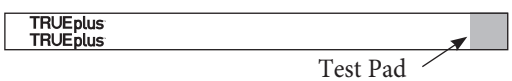
For low carbohydrate dieters who are not diabetic, low intake of complex carbohydrates and sugars promotes use of ketones from fat stores rather than blood glucose as the primary source of energy for the body. When this occurs, the body produces a steady state of ketones (ketosis).[1]

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.[2]

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.

Precautions

- TRUEplus Ketone Test Strips are for *in vitro* diagnostic use only (outside the body). **DO NOT CONSUME.**
- TRUEplus Ketone Test Strips are used for urine testing only. **DO NOT USE for blood testing.**
- If ketones are present, please see a Doctor to have your ketone level tested.
- 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 2 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. After 15 seconds, match Test Pad to color chart on vial label. Ignore any color changes after 15 seconds.
   NOTE: *Color Chart blocks give approximate values; 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 (160 mg/dL). Normal urine usually gives negative results.[3]

Unusual Test Results

1. Check 'Use By' date and 'Opened' date. If 'Use By' date has passed or it is 2 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.

If you have questions or concerns, call 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: Strongly colored urine samples may mask color of Test Pad and may cause negative result to appear as positive. Compounds that contain a sulfhydryl group, such as MESNA (2-mercaptoethane-sulfonic acid), may cause false positive results.[4]

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 (positive, 160 mg/dL). Each color block represents a range of ketone values. 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: 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. Ketosis: Is it Safe? Why do some people say it's dangerous? Lean for Life Online. Retrieved 10March04 from www.ketosis-Ketoacidosis-difference.com.
2. Diabetes - Urine Ketone Testing, Dept. of Nursing Services & Patient Care. Virtual Hospital. Retrieved 10March04 from www.vh.org/adult/patient/internalmedicine/urineketonetesting.
3. Ketoacidosis. American Diabetes Association. Retrieved 10March04 from www.diabetes.org/type-1-diabetes/ketoacidosis.jsp.
4. G. Csako, CLINCHEM, 33/2, 289 (1987).

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