Ketostix® Reagent Strips/Test Information and Procedure

Urine Test for Ketone (Acetoacetic Acid)

SUMMARY AND EXPLANATION:

The strips provide a fast, convenient way of testing urine for the presence and concentration of acetoacetic acid (ketone). This substance when found in the urine provides information on carbohydrate and fat metabolism.[1,2]

Acetoacetic acid can be found in the urine from diabetics and is more commonly referred to as a "ketone body." Use of KETOSTIX® Reagent Strips can alert you and your doctor or diabetes educator to changes in your condition for which adjustments in your diet and/or medication may be needed. Carefully follow the testing schedule your doctor or educator establishes.

CHEMICAL PRINCIPLES OF THE PROCEDURE:

The ketone test is specific for acetoacetic acid and is based on the development of colors ranging from buff-pink to maroon when acetoacetic acid reacts with nitroprusside.

REAGENTS:

7.1% w/w sodium nitroprusside; 92.9% w/w buffer.

WARNINGS AND PRECAUTIONS:

KETOSTIX® Reagent Strips are for *in vitro* diagnostic use. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29CFR 1910.1200(d).

STORAGE AND HANDLING:

Never use bottled KETOSTIX® Reagent Strips past the expiration date printed on the bottle label.

To keep KETOSTIX® Reagent Strips fresh, follow these suggestions carefully. Keep your finger or other objects from touching the reagent area before testing. Store at room temperatures between 59°-86°F (15°-30°C). Do not store the bottle in direct sunlight.

Keep unused reagent strips in the original bottle with the cap tightly closed. Always replace the cap immediately and tightly after removing a strip. A new bottle of strips can be used for six months after being first opened. Always write the date you first opened the bottle on the bottle label. **Do not use product (opened or unopened) after expiration date. Use of strips beyond the expiration date may yield low results.** Never transfer reagent strips to another bottle. Do not remove desiccant from bottle. The desiccant absorbs moisture and keeps the strips dry. Never put cotton or other materials in the bottle. If the reagent area is ever discolored or darkened, throw the strip away and use a strip from a new bottle.

SPECIMEN COLLECTION AND PREPARATION:

Collect fresh urine in a clean, dry container and test it as soon as possible, or alternatively, pass the reagent pad through the urine stream. In clinical use, if testing cannot be done within an hour after collecting a urine specimen, refrigerate the specimen immediately and let it return to room temperature before testing.

Use of urine preservatives may affect test results. For hospital and clinical use, further information regarding the effects of urine preservatives on Ascensia Diabetes Care urinalysis products may be obtained by contacting our Customer Service Department and requesting Technical Report No. 8-82.

QUALITY CONTROL IN HOSPITAL USE:

To check KETOSTIX® Reagent Strip reactivity, test known positive and negative specimens or controls. It is best to do this whenever a new bottle is opened. Use a *control* that contains the acetoacetic acid ketone body.

NOTE: Due to specificity for acetoacetic acid, the ketone reagent area may not react with some commercial controls.

RESULTS:

Results with KETOSTIX® Reagent Strips are obtained directly from comparison to the Color Chart. The color blocks represent nominal values; actual values will vary around the nominal values.

Ketone results are read from the Color Chart as negative or varying degrees of positive which indicate the relative amounts of ketone (acetoacetic acid) present. The color blocks represent Negative, Trace (5 mg/dL), Small (15 mg/dL), Moderate (40 mg/dL) and Large (80-160 mg/dL). Proper read time is critical for optimal results.

The ketone reagent area is most accurate when testing urines of specific gravity between 1.010 and 1.020.

IF TEST RESULTS SEEM QUESTIONABLE:

1. Check the EXPIRATION DATE printed on the bottle label. If the date has passed, discard and retest with strips from a new bottle. Check the date you first opened the bottle and if 6 months have passed, throw the strips away and use a new bottle of KETOSTIX® Reagent Strips.
2. Test the urine again with a strip from a new bottle and compare results. **If a problem cannot be identified or corrected, call our Customer Service Department, toll free 1-800-348-8100, Monday through Sunday, 8:00 am through 12:00 Midnight, Eastern time, or consult your doctor, diabetes educator, pharmacist, Self Testing Center or local product representative for advice on testing technique and results.**
3. *For Professional Use:* Run a Control Test to check performance of the whole system (reagent strip and technique), using known positive and negative specimens or controls.

EXPECTED VALUES:

Normal urine specimens ordinarily yield negative results with the KETOSTIX® reagent area. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.[3-5] In ketoacidosis, starvation or other abnormalities of carbohydrate or fat metabolism, ketones may appear in urine in large amounts before serum ketone is elevated.[6]

LIMITATIONS OF PROCEDURES:

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method. KETOSTIX® results should never be used as the sole basis for adjusting insulin dosage.

Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Macrodantin®, Furadantin®), and riboflavin, may affect the readability of the ketone reagent area on the KETOSTIX® Reagent Strips. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted as a false positive.

False positive results (Trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.

SPECIFIC PERFORMANCE CHARACTERISTICS:

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors: the variability of color perception; the presence or absence of inhibitory factors typically found in urine, the specific gravity, and the pH (see LIMITATIONS OF PROCEDURES section); and the lighting conditions under which the product is read. Because the color of each reagent area changes as the analyte concentration increases, the percentage of specimens detected as positive will increase with the analyte concentration.

Each color block represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level will usually be within one level of the true concentration.

The test reacts with acetoacetic acid in urine. It does not react with acetone or beta-hydroxybutyric acid. In a majority of cases, the reagent area detects 5 to 10 mg/dL acetoacetic acid. Some high specific gravity-low pH urines may give reactions up to and including Trace (5 mg/dL). Clinical judgment is needed to determine the significance of reactions up to and including Trace.

AVAILABILITY:

KETOSTIX® Reagent Strips in bottles of 100 strips (#2881) or 50 strips (#2880) are available from local authorized Ascensia Diabetes Care Distributors, Self-Care Centers, or selected retail pharmacies. www.contournextstore.com

REFERENCES:

1. Cecil, R. L. and Loeb, R. F.: A Textbook of Medicine, W. B. Saunders, Co., Philadelphia, 1959, 10th ed., pp 618-619.
2. Engel, F. L. and Amatruda, T. T.: Ann. N. Y. Acad. Sci. 104, Art 2, 753-771 (1963).
3. McGarry, J. D., Lilly, Lecture 1978: New Perspectives in the Regulation of Ketogenesis. *DIABETES* 28, May, 1978, 517-523.
4. Williamson, D. H.: Physiological ketoses, or why ketone bodies? *Postgraduate Medical Journal* (June Suppl. 1971), 371-375.
5. Paterson, P., Sheath, J., Pincus, T. and Wood, C.: Maternal and Fetal Ketone Concentrations in Plasmas and Urine, *The Lancet*: April 22, 1967, 862-865.
6. Fraser, J., Fetter, M.C., Mast, R. L. and Free, A. H.: Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk, *Clin. Chem. Acta II* (1965) 376-378.

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Reagent made in U.S.A.; further processed and packaged in Poland.

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ASCENSIA Diabetes Care

TN06516D

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Rev. 05/17 USA

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5050 1st Ave S, Suite 101
Seattle, WA 98134
206.587.0800
dsg.rrd.com

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V0 05/06/17 Initial Build
V1 05/30/17 DMC Annotations
V2 06/15/17 DMC Annotations
V3 06/28/17 DMC Annotations

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Urine Test for Ketone (Acetoacetic Acid)

WHY DO I NEED TO TEST FOR KETONE?

Ketone is a substance which is usually not harmful when found in small amounts in the urine. This could happen in dieting and, when identified, gives you information on carbohydrate and fat metabolism.

However, when you have too much of this substance in your body it can be dangerous and especially dangerous for a person with diabetes.

If you are a person with diabetes, you may produce ketones in urine whether you are insulin dependent (Type I) or non-insulin dependent (Type II). A person with Type I diabetes is more likely to spill ketones in the urine because they are more likely to burn too much fat.

If you burn too much fat and produce a lot of ketones, your diabetes may be out of control. Then you may develop a complication called diabetic KETOACIDOSIS. This can lead to a coma. You need to take fast action when you see the ketone warning signal. You should contact your doctor or diabetes educator immediately. Your doctor or educator can tell you how to change your medication/insulin dose or your food intake to bring your diabetes back into control and to prevent ketoacidosis.

WHEN SHOULD I TEST FOR KETONE?

1. When you have a cold, the flu or any other kind of illness.
2. When your urine sugar test results show you are spilling large amounts of sugar (2% or more for two or more tests in a row or several days in a row).
3. When you "feel" the signs of high blood sugar (over 240 mg/dL) or when your blood sugar is well over the range your doctor or educator has set for you (if you do blood glucose monitoring).
4. When you are under stress e.g., at home, at school, at work, or on a vacation.
5. Regularly during pregnancy.

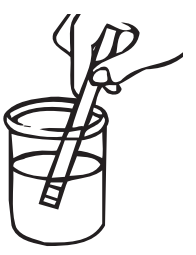
HOW DO I DO THE TEST?

Materials needed:

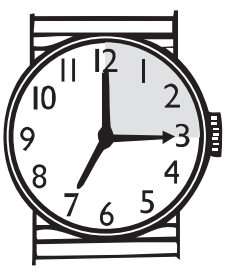
- KETOSTIX® Reagent Strips
- Timer or watch with second hand

1. Remove the strip from bottle. **(Replace the cap immediately and tightly.)** *Do not* touch the test area of the strip. Check the EXP. DATE printed on the bottle label. If the date has passed, discard and retest with test strips from a new bottle. If the bottle has been opened, check the date you recorded when you first opened the bottle and if 6 months have passed, throw the test strips away and use a new bottle of KETOSTIX® Reagent Strips. **Do not use product (opened or unopened) after expiration date. Use of strips beyond the expiration date may yield low results.**

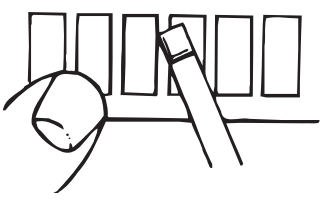
2. Dip the test end of the strip into a fresh urine sample and remove it immediately (drawing edge of strip against the rim of the urine container to remove excess urine), or pass the test end of the strip through a stream of urine.



3. Begin timing.



4. AT EXACTLY 15 SECONDS, match the reagent area to the ketone color chart. Ignore color changes that occur after 15 seconds.



5. Record the result.
   NOTE: If the test shows a moderate or large amount of ketone, call your doctor or diabetes educator.



If a problem cannot be identified or corrected, call our Customer Service Department, toll free 1-800-348-8100, Monday through Sunday, 8:00 am through 12:00 Midnight, Eastern time, or consult your doctor, diabetes educator, pharmacist, Self-Care Center or local Product Representative for advice on testing technique and results.