Department of Laboratories
St. Louis, MO 63110

PROCEDURE: KETOSTIX - URINE TEST FOR KETONE (ACETOACETIC ACID)

ISSUE DATE: January 1997 **REVISION DATE:** September 2010
REVIEWED DATE: May 2015

PRINCIPLE:

Acetoacetic acid can be found in the urine from diabetics and is more commonly referred to as a "ketone body". 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.

SPECIMEN:

Collect fresh urine in a clean dry container according to nursing guidelines. If testing cannot be performed within an hour of collection, refrigerate the specimen and let it return to room temperature before testing. DO NOT use urine collected in a preservative.

REAGENTS / EQUIPMENT:

- KetoStix reagent strips
- Quantimetrix Dropper Plus Urine Dipstick Control (levels 1 and 2)

QUALITY CONTROL:

1. Two levels (normal and abnormal) of quality control are required each day of patient testing. The urine dipstick controls are stored and 2 – 8ºC before initial use. When stored at 2 – 8ºC, the controls are stable until the expiration date on the label. After initial use, the open bottles can be stored at room temperature for 30 days. Date the vial when opened.
2. If QC was stored in refrigerator, allow to reach room temperature – about 15–30 minutes. Floors at SLCH store them at room temperature.
3. Mix QC gently by inversion to assure adequate mixing. Avoid foaming.
4. Remove cap and invert bottle.
5. While holding the dipstick, gently squeeze the dropper bottle, placing a drop of QC on the reagent pads of the dipstick.
6. Thoroughly saturate each reagent pad on the dipstick.
7. Turn dipstick to the side and drain the excess control onto absorbent material.
8. Read the dipstick visually and record the results on the urine QC sheet.
9. Wipe off the dropper tips and recap the bottles.
10. If the results falls outside of expected range, repeat the testing and check expiration dates of the QC vials and the reagent strips. If the QC fails again, open a new vial of QC. If QC fails a third time, open a new vial of KetoStix. DO NOT proceed with patient testing until QC is acceptable. Send all specimens to the Core Lab for testing. 8West performs QC on each vial daily when used for patient testing.

PROCEDURE:

1. Collect urine according to nursing guidelines.
2. Label specimen with patient information (name / medical record number)

3. Remove strip from the vial – being careful not to touch the testing area.
4. Dip the test area into the urine so that the test pad is completely saturated.
5. Remove immediately to avoid dissolving of the reagent.
6. While removing, run the edge of the strip against the rim of the urine cup to remove excess urine.
7. Begin timing.
8. At **EXACTLY** 15 seconds, match the reagent area to the ketone color chart on the vial.
9. Disregard any color change after the initial 15 seconds.
10. Record the result in the patient chart.

PROCEDURAL NOTES:

1. Never use expired reagent strips. Use of expired strips may yield low results. Strips expire 6 months after opening or manufacturer's date on the vial. New lots are checked by the lab and documented.
2. KetoStix should never be used as the sole basis for adjusting insulin dosage.
3. The ketone reagent area is most accurate when testing urine of specific gravity between 1.010 and 1.020.
4. Detectable levels of ketone may occur during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.
5. KetoStix only detect one of the two forms of circulating Ketone Bodies, Acetoacetate. It does not detect betahydroxybutyrate. In the early stages of DKA, the cellular redox potential NAD/NADH is reduced and the primary ketone body formed is betahydroxybutyrate. With treatment, acetoacetate production increases and suggests more ketone formation when in fact ketosis may be lessened.

LIMITATION OF PROCEDURE:

1. Substances that cause abnormal urine color, such as drugs containing azo dyes, nitrofurantoin and riboflavin, may affect the readability of the ketone reagent area. The color development on the pad may be masked, or a color reaction may be produced that could be interpreted as a false positive.
2. False positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites.
3. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical reaction.
4. The test reacts with acetoacetic acid in urine. It does not react with acetone or betahydroxybutyric acid.
5. Some high specific gravity and low pH urine may give reactions up to and including trace results.
6. Ketone testing performed on 8West is done with Diabetic patients for Education purposes. KetoStix lots are checked by the lab for 8West Education of Diabetics. Urine Quality Control is performed And documented.

Quality Control:
Quality Control logs for KetoStix testing is reviewed by the Point of Care Staff at least bi-weekly.

REFERENCE RANGES:

Normal urine specimens ordinarily yield negative results.

REFERENCES:

1. Bayer KetoStix Reagent Strip package inserts, Bayer Corporation, revised 9/95.

Donna Walck Technical Coordinator
Written By:

_____	_____
Technical Supervisor	Date
_____	_____
Medical Director	Date

Annual Review: Medical Director/Designee	Date
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Location of hard copy location(s): Core Lab Office
See Test Methods / Test Locations (POC.1.0002.0)
_____
_____
_____

Date Archived: _____