**INTRODUCTION**

1. **Keto-Test** is a test strip used for semi quantitative estimation of Glucose and Ketone in urine sample.
2. **Keto-Test** is a disposable, ready to use plastic strip on which are affixed 2 reagent areas for testing : Glucose and Ketone.
3. When dipped in urine sample the strip colour is read visually, within 40 sec., requiring no additional laboratory equipment for testing.
4. The **Keto-Test** test strips are packed in an airtight plastic bottle containing a dessicant.

**PRINCIPLE**

Glucose : This test is based on a double sequential enzyme reaction. Glucose Oxidase converts urine Glucose to gluconic acid and hydrogen peroxide. Subsequently, Peroxidase converts hydrogen peroxide into water and nascent oxygen. The nascent oxygen liberates iodine from potassium iodide to produce colours ranging from green to brown depending on the urine glucose concentration.

Ketone : The test is based on the principle of Rothera’s test. In this reaction, acetoacetic acid in an alkaline medium will react with sodium nitroprusside to produce a purple colour. The term ketones represents three intermediate products of fat metabolism, namely acetone, acetoacetic acid and β-hydroxybutyric acid. The test strip is specific only to acetoacetic acid. It does not measure β-hydroxybutyric acid and is only slightly sensitive to acetone if glycine is present.

**STORAGE**

**Keto-Test** is for in vitro diagnostic use. Store the product at room temperature under 35°C. Do not refrigerate. The product should not be used after expiration date.

**PROCEDURE**

This procedure must be followed exactly to achieve reliable results.

1. Collect fresh, well-mixed, uncentrifuged urine in a clean and dry container.
2. Remove one strip at a time, from the bottle and replace cap immediately and tightly.
3. Dip the reagent areas into urine for 1 to 2 seconds. While removing the strip from the urine run the edge of the strip along the container’s wall and tap to remove excess urine from the strip.

4. Hold the strip close to the colour chart provided on the label and match carefully. The glucose results should be read at 30 seconds and the ketone results at 40 seconds. The colour chart should be matched under good light (but not direct sunlight).

5. Avoid touching the strip directly on the colour chart as this will result in soiling the chart.

6. Interpret the results if the colour obtained falls between two adjacent colour blocks.

7. Colour changes that occur after 40 seconds are of no quantitative diagnostic value.

**WARNINGS AND PRECAUTIONS**

1. Do not transfer the strips from its original bottle to any other bottle.
2. Do not remove the dessicant from the bottle.
3. Replace cap immediately and tightly after removing the reagent strips to maintain reagent reactivity.

4. **Keto-Test** should be protected from moisture. This will prevent deterioration during storage.
5. Care must be taken not to touch the test reagent areas of unused strips.
6. All test reagent strips must be used within 4 months from the date of opening the bottle.
7. Working areas and specimen containers should be free of detergents and other contaminating substances.
8. Dip test areas in urine completely, but briefly (1-2 seconds) to avoid dissolving out the reagents from test area.
9. Read test results carefully at the time specified.

EXPECTED VALUES

Glucose: Normally no glucose is detectable in the urine, although a minute amount is excreted by the normal kidneys. A slight green colour which is less than trace colour is insignificant.

Ketone: Normal urine specimens ordinarily yield negative results with this reagent. Detectable levels of ketones may occur in urine during physiological test conditions such as fasting, pregnancy and frequent strenuous exercise (Ref. 1, 2, 3). In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine in large amounts before serum ketone is elevated. Some high specific gravity / low pH urines may give reactions up to including Trace. Clinical judgement is needed to determine the significance of reactions up to and including Trace.

RESULT INTERPRETATION

Glucose and Ketone result interpretation is done by direct comparison with the colour blocks on the bottle label.

**Glucose:**
- Negative: No significant urine glucose present.
- Trace: approx. 100 mg% (1/10 g/dl)
- +: approx. 250 mg% (1/4 g/dl)
- ++: approx. 500 mg% (1/2 g/dl)
- +++: approx. 1000 mg% (1 g/dl)
- ++++: approx. 2000 mg% (2 g/dl) or more

**Ketone:**
- Negative: No significant urine ketone present (Acetoacetic acid).
- Trace: approx. 15 mg%
- Small: approx. 15 mg%
- Moderate: approx. 40 mg%
- Large: approx. 80 - 160 mg%

PROCEDURE LIMITATIONS

**Glucose:**
- High specific gravity in combination with high pH, may reduce sensitivity of the test resulting in a false negative result at low concentrations of glucose. Ascorbic Acid concentration of 50-75 mg/100 ml or greater may cause false negative results for specimens containing small amounts of glucose (100 mg/dl). Large amounts of ketone bodies reduce the sensitivity of the test.

**Ketone:**
- The nitroprusside reaction is subject to a minimum of outside interference. Large concentrations of levodopa may cause false positive reactions, and specimens collected after diagnostic procedures employing phthalene dyes may produce an interfering red colour in the alkaline test medium. The presence of phenylketones in the urine can also distort the colour reaction. Falsely decreased values owing to the volatilization of acetone and the breakdown of acetoacetic acid by bacteria will be seen in improperly preserved specimens.

QUALITY CONTROL

Check with known negative and positive urine samples or controls every time a new bottle is opened.

REFERENCES