



2. Remove strip from pouch for immediate use. Hold the plastic end of the strip. Completely immerse reagent area of the strip in urine sample and remove immediately to avoid dissolving out reagent area.
3. Remove the strip slowly avoiding any spilling. Run the edge of the strip against the rim of the urine container to remove excess urine.
4. Exactly 40 seconds after removing from the specimen, compare reagent area to the color chart on the pouch. (Hold strip close to color block and match carefully. Do not touch the color block with the test area).

RESULTS

Results with URS-1K are reported as qualitative values, by comparing the color of the test strip to the color chart and matching it with the closest color block.

LIMITATIONS OF TEST

1. Color reaction that could be interpreted as “positive” may be obtained with urine specimens containing MESNA or large amounts of phenylketones or L-dopa metabolites.²
2. This test is only for screening; all positive results should be confirmed by a health care provider and/or a quantitative method where accuracy and sensitivity are greater.
3. Interpretation of results will depend upon several factors: the variability of color perception; the presence or absence of inhibitory factors typically found in urine, and the specific gravity; and the lighting conditions under which the product is used.
4. Do not use if individual performing the test is color blind, or has any vision impairment.
5. Contamination of both urine sample and reagent strips must be avoided.

EXPECTED VALUES

Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.⁴⁻⁶ In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.⁷

PERFORMANCE CHARACTERISTICS

The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone. The

reagent area detect as little as 5 – 10 mg/dl acetoacetic acid in urine.

As with any visual test, accuracy is a function of the manner at which the color blocks on the pouch are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye.

TROUBLESHOOTING

(Protection of URS-1K against ambient moisture, light and heat is essential to guard against altered reagent activity).

Discoloration or darkening of reagent area may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, the following steps are recommended:

- (1) Confirm that the product is within the expiration date shown on the pouch.
- (2) Check performance against known positive control materials.
- (3) Retest with fresh product.

REFERENCES

1. Free, A.H and Free, H.M.: Urinalysis, Critical Discipline of Clinical Science. *CRC Crit. Rev. Clin. Lab. Sci.* 3(4): 481-531; (1972).
2. Tietz, N.W.: Clinical Guide to Laboratory Tests; W.B. Saunders Company, (1976).
3. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry 2nd Ed. 2205; (1994).
4. McGarry, J.D.: Lilly Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. *Diabetes* 28: 517-523 May, (1978).
5. Williamson, D.H.: Physiological ketoses, or Why Ketone Bodies? *Postgrad. Med. J.* (June Suppl.): 371-375: (1971).
6. Paterson, P. et al.: Maternal and Fetal Ketone Concentrations in Plasma and Urine. *Lancet*: 862-865; April 22, (1967).
7. Fraser, J. et al.: Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. *Clin. Chem. Acta II*: 372-378; (1965)
8. Henry, J.B. et al.: Clinical Diagnosis and Management by Laboratory Methods, 16th Ed. Philadelphia: Saunders; (1979).

URS-1K: 10/01

CLIAwaived.comTM

CLIAwaived.com - 4332 Corte de la Fonda - San Diego, CA 92130

Toll Free : (888) 882-7739 - Phone (858) 481-5031

FAX: (801) 720-7568 - www.cliawaived.com

**URINE REAGENT STRIPS
(URS-1K)
Tests for Ketone****INTENDED USE**

URS-1K reagent strips provide a fast, convenient way of screening for ketone (acetoacetic acid) in urine. Ketone found in the urine test provides information regarding the status of carbohydrate and fat metabolism. This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

DEVICE DESCRIPTION

URS-1K strips for urinalysis are firm plastic strips to which a ketone reagent area is affixed. URS-1K strips are packaged along with a drying agent in an aluminum pouch. Each strip is ready to use upon removal from the pouch. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the pouch.

WARNINGS AND PRECAUTIONS

1. Urine reagent strips are for *in vitro* diagnostic use only. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).
2. Any visual impairment, such as color blindness, will affect accuracy of reading the results.
3. To obtain best results, use fresh urine.
4. Follow directions exactly.
5. For optimal results, accurate timing is essential.
6. Exposure of URS-1K to light, moisture, or heat will cause deterioration and decrease reactivity.

CONDITIONS UNDER WHICH THE DEVICE SHOULD AND SHOULD NOT BE USED

1. Comparison to the color chart is dependent on the interpretation of the individual. It is therefore recommended that all users be tested for color blindness.
2. Work areas and specimen containers should be free of contaminating substances.
3. When testing, dip test areas in urine completely, but briefly, to avoid dissolving out the reagents. Read test results carefully at specified time in a good light with the test area held near the color chart.

SETUP INSTRUCTIONS

Work areas and specimen containers should be free of contaminating substances. Collect urine in a clean container and test as soon as possible. If testing cannot be performed within one hour, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

READING THE RESULTS

When a strip is dipped in urine, the test area changes color according to the amount of ketone present in the urine. The developing color of the test area is compared to the color blocks on the color chart after time specified.

STORAGE AND HANDLING

NOTE: All warnings, precautions, and proper storage procedures must be followed to avoid deterioration and insure reactivity of URS-1K.

1. Store pouch at temperatures between 15°- 30°C (59°- 86° F) and out of direct sunlight.
2. Do not use after expiration date.
3. Do not touch test areas of the reagent strip.

MATERIALS PROVIDED

1. Aluminum pouch containing one strip of URS-1K.
2. A visual comparison color chart for reading test results is printed on the pouch.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clean, dry container for urine collection.
2. Timer or watch capable of measuring accurately in seconds.

PROCEDURE (MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS.)

Note: A positive result from a screening is considered to be a **screened "presumptive" or "indeterminate" result** and should **never** be interpreted as final without a follow-up with a health care provider, confirmation testing, or both.

1. Collect urine specimen in a clean, dry container. Mix well immediately before testing. If urine specimens are not tested within 1-hour, store at 2-8°C and bring to room temperature before testing.