

TECO DIAGNOSTICS 1268 N. Lakeview Ave. Anaheim, CA 92807, USA. 1-800-222-9880

INTENDED USE

URS-1A reagent strips provide a fast, convenient way of screening for Vitamin C (ascorbic acid) in urine. Vitamin C found in the urine test provides information regarding the status of Vitamin C absorption and consumption. This test is based on the action of a complex chelating agent with a polyvalent metal ion in its higher state and an indicator dye that can react with the metal ion in its lower state to produce a color change from blue-green to yellow. The colors range from blue-green for a "Negative" reading to yellow for a "Positive" reading.

DEVICE DESCRIPTION

URS-1A strips for urinalysis are firm plastic strips to which Vitamin C reagent areas are affixed. URS-1A strips are packaged along with a drying agent in a plastic bottle. 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 color chart.

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-1A 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 Vitamin C 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

Store at room temperature between 15°-30°C (59°-86°F) and out of direct sunlight. Do not use after expiration date.

TEST PROCEDURE

- 1. Remove from the bottle only enough strips for immediate use and twist the cap back tightly.
- 2. Completely immerse reagent areas of the strip in fresh, well-mixed urine. Remove the strip immediately to avoid dissolving out the reagent areas.
- 3. While removing, touch the side of the strip against the rim of the urine container to remove excess urine. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess urine and avoid running over (contamination from adjacent reagent pads.)
- 4. After 30 seconds, compare the reagent pad to the color block on the color chart and read at the times specified. Proper read time is critical for optimal results.
- 5. Obtain results by direct color chart comparison.

RESULTS

Results with URS-1A are obtained by direct comparison of the color blocks printed on the color charts. The color blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test, result or method.

PERFORMANCE CHARACTERISTICS

This test can detect ascorbic acid in concentrations as low as 10 mg/dl in urine.

EXPECTED VALUES

The daily urinary output of ascorbic acid varies with the intake: it approximately half of the intake. The average urinary output ranges from 20-30 mg/day. If detect ascorbic acid in urine, stop taking ascorbic acid for 24 hours and retest.

False negative and weak reaction of glucose, blood and bilirubin may be observed if:

- Glucose: more than 50 mg/dl ascorbic acid in the sample.
- Bilirubin: more than 50 mg/dl ascorbic acid in the sample.
- Blood: more than 10 mg/dl ascorbic acid in the sample.



REFERENCES

- 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. Yoder, J.Adams, E.C., and Free. H.M.: Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH. *Amer. J. Med Tech.* 31:285; (1965).
- 3. Tietz, N.W.: Clinical Guide to Laboratory Tests; W.B. Saunders Company, (1976)
- 4. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry 2nd Ed. 2205; (1994).
- Henry, J.B. et al.: Clinical Diagnosis and Management by Laboratory Methods, 16th Ed. Philadelphia: Saunders; (1979).

URS-1A: 09/2012

Manufactured by:



TECO DIAGNOSTICS 1268 N. Lakeview Ave. Anaheim, CA 92807, USA. 1-800-222-9880

CE

Authorized Representative: Emergo Europe Molenstraat 15 2513 BH The Hague The Netherlands