

MeriCheck 3™ Urine Reagent Strips

SUMMARY

Merit Pharmaceutical MeriCheck 3™ Urine Reagent Strips (URS) for Urinalysis are firm plastic strips to which several different reagent areas are affixed. Merit MeriCheck 3™ Urine Reagent Strips provide tests for Ketone (Acetoacetic acid), pH, and Ascorbic Acid (Vitamin C) in Urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria.^{1,2} Please refer to the outside box and bottle label for the specific test parameters of the product.

Merit Pharmaceutical MeriCheck 3™ Urine Reagent Strips are packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are required.

TEST PRINCIPLE

Ketone: 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.

pH: This test is based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

Ascorbic Acid: 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.

REAGENTS (Based on dried weight at time of impregnation)

Ketone: 7.7% w/w sodium nitroprusside balanced with buffer and non-reactive ingredients.

pH: 0.2% w/w methyl red; 2.8% w/w bromothymol blue; 97% w/w nonreactive ingredients.

Ascorbic Acid: 5.8% w/w ferric chloride; 4.9% w/w DTPA; 1.2% dipyriddy; 89.1% w/w buffer and nonreactive ingredients.

WARNINGS AND PRECAUTIONS

Urine Reagent Strips are for *in vitro* diagnostic use. Do not touch test areas or Urine Reagent Strips.

STORAGE

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

RECOMMENDED HANDLING PROCEDURES

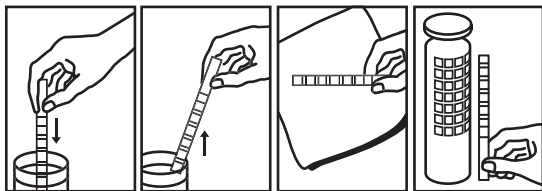
All unused strips must remain in the original bottle. Transfer to any container may cause reagent strips to deteriorate and become nonreactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container and test as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

TEST PROCEDURE

1. Remove from the bottle only enough strips for immediate use and replace cap 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. Compare each reagent area to its corresponding color blocks 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.



Note: All reagent areas may be read between 1-2 minutes for screening positive urine from negative urine. Changes in color after 2 minutes are of no diagnostic value.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

RESULTS

Results are obtained by direct comparison of the color blocks printed on the bottle label. The color blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.

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

Ketone: 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.³

pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "running over" may occur, in which the acid buffer from the protein reagent area run onto the pH area, causing a false lowering in the pH result.

EXPECTED VALUES

Ketone: 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 exercise⁶⁻⁸ in starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.⁹

pH: newborn: 5-7 thereafter: 4.5-8 average: 6.

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

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Merit Pharmaceutical MeriCheck 3™ Urine Reagent Strips (URS) have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, Urine Reagent Strips (URS) have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)

For visually read strips accuracy is a function of the manner in which the color blocks on the bottle label 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. It is for this reason that users are encouraged to develop their own standards of performance.

Ketone: 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 detects as little as 5-10 mg/dl acetoacetic acid in urine.

pH: The pH test area permits quantitative differentiation of pH values to one unit within the range of 5-9. pH reading is not affected by variation in the urinary buffer concentration.

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

BIBLIOGRAPHY

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Manufactured for:
Merit Pharmaceutical
2611 N San Fernando Rd
Los Angeles, CA
(323) 227-4831
www.meritpharm.com

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