
This package insert covers the test configurations above. This insert describes the test configurations displayed above. This insert describes the test configurations displayed above.

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 urine preservative is sufficient for all specimens recommended. If fasting cannot be performed within one week after voiding, refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing.

TEST PROCEDURE
1. Remove each 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 prevent any contaminate or excess urine from being transferred to the 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. Obtain results by direct color chart comparison.

NOTE: All reagent areas except Leukocytes may be read between 1-2 minutes for results. Bilirubin and Ketones may be read from negative urine. Changes in color after 2 minutes are no diagnostic values.

QUALITY CONTROL
For best results, performance of reagent strips should be confirmed by testing known concentrations of analytes for each reagent area. 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
The color blocks 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 of the color blocks is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these tests be color blind.

As with all laboratory test dipsitive diagnosis of therapeutic decisions should not be made on any test result alone. This package insert covers the test configurations above. This insert describes the test configurations displayed above. This insert describes the test configurations displayed above.
**KETONE:** Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine due to physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.\(^5\) In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively large amounts before serum ketones are elevated.\(^6\)

**SPECIFIC GRAVITY:** Random urine may vary in specific gravity from 1.003-1.040. Twenty-four hour urine from normal adults with normal diets and normal fluid intake will have a specific gravity of 0.996-1.022\(^6\) in severe renal damage the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

**BLOOD:** Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably found in the urine of menstruating females.

PH: newborn: 5-7; thereafter: 4.5-8 average: 6.\(^3\)

PROTEIN: In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney.\(^6\) A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

**UROBILINOGEN:** In a healthy population, the normal urine urobilinogen range obtained with this test is 0-2.10-1 Ehrlich Unit/ml. A result of 2.0 EU/dl may be of clinical significance and the same patient sample should be evaluated further.

NITRITE: Normally no detectable amount of nitrite is present in urine.\(^6\) The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test range from as low as 40%, in instances where little bladder incubation occurred, to as high as 80% in instances where a minimum of 4 hours incubation occurred.

**LEUKOCYTES:** Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

**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/dl. If ascorbic acid is detected 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.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The performance characteristics of CLIA-X Urine Reagent Strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, the CLIA-X Urine Reagent Strips 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. This is for the reason that users are encouraged to develop their own standards of performance.

**GLUCOSE:** This test is specific for glucose; no substances excreted in urine other than glucose is known to give a positive result. The test area does not react with lactate, galactose, fructose, or reducing matter of drugs; e.g. salicylates and nitrate acid. This test may be used to determine whether the reducing substances found in urine are glucose. Approximately 100 mg/dl glucose in urine is detectable.

**BILIRUBIN:** The test has a sensitivity of 0.0-4.0 mg/dl bilirubin in urine. The test is considered specific for bilirubin in urine.

**KETONE:** The ketone test area provides semi-quantitative results and react 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.

**SPECIFIC GRAVITY:** The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, the specific gravity test correlates within 0.005 with values obtained with the reflective index method.

**BLOOD:** At the time of reagent manufacture, this test when read as instructed has sensitivity to free hemoglobin of 0.015 mg/dl or 5-10 intact red blood cells/ml urine. This test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

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

**PROTEIN:** The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones proteins, and mycoprotein; a negative result does not rule out the presence of these other proteins. The test area is sensitive to 15 mg/dl albumin. Depending on the inherent variability in clinical urine lessor concentration may be detected under certain conditions.

**UROBILINOGEN:** This test will detect urobilinogen in concentrations as low as 0.2 EU/dl urine. The absence of urobilinogen in the specimen being tested cannot be determined with this test.

**NITRITE:** At the time of reagent manufacture, this test has sensitivity to sodium nitrite of 0.075 mg/dl. Comparison of the reacted reagent area on a white background may aid in the detection of low levels of nitrite ion, which may otherwise be missed. This test is specific for nitrite and will not react with substances normally excreted in the urine.

**LEUKOCYTES:** This test can detect as low as 10-15 WBC/million. This test will not react with erythrocytes or bacteria common in urine.

**ASCORBIC ACID:** This test can detect acetic acid in concentrations as low as 10 mg/dl urine.

**BIBLIOGRAPHY**


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