Separate sets of color blocks are given for erythrocytes and hemoglobin. Scattered or compacted green dots on the yellow test pad are indicative of intact erythrocytes. A uniform coloration of the test pad is indicative of free hemoglobin, myoglobin, or hemolyzed erythrocytes in the urine.

Reagent Composition
See the outside of the test strip box for reagent composition.

Warnings and Precautions:
For in vitro diagnostic use.

Warnings:
Avoid contact with skin and mucous membranes; flush affected areas with copious amounts of water. Get immediate medical attention for eyes or if ingested.

Exercise the normal precautions required for handling all laboratory reagents.

Gloves:
The "universal precautions" recommended by the Centers for Disease Control and Prevention should be followed when blood or body fluids are handled. These precautions include wearing gloves.

Storage and Stability: Store test stripes at 2°C (36°F) - 30°C (86°F). Do not freeze.

Chemstrip urine test strips are stable in the original cellophane strip until the listed expiration date. In order to avoid exposure to moisture, the vial must be closed immediately after removal of a strip, using the original stopper which contains a drying agent.

Specimen Collection and Preparation:
Chemstrip urine test strips may be used on freshly voided urine specimens or on urine collected under special conditions, such as first-morning specimens and post-prandial urines. The urine must be collected in a clean container and should be tested as soon as possible after collection (do not centrifuge or use preservatives).

It is important to use fresh urine to obtain the best results with the test for urine bilirubin and urobilinogen as these compounds are very unstable when exposed to room temperature and daylight. If testing cannot be performed within two hours after collection, the specimen should be refrigerated at 2°C - 8°C immediately and returned to room temperature before testing. Do not refreeze. Urobilinogen in urine is tested. Urobilinogen in urine is not corrected.

Urine should be collected in a container which allows complete immersion of the reagent pads on the test strip. If a clear voided urine is not collected, a positive test result for bilirubin or bilirubin in urine due to interference with the urine stream is normal. If a clear voided urine is not collected, a positive test result for bilirubin or bilirubin in urine due to interference with the urine stream is normal.

Procedure:

Materials Provided: 1 vial containing 100 Chemstrip urine test strips. A visual comparison scale for reading test results is printed on the vial label.

Material Required, But Not Provided: A timer and a clean specimen collection container.

It is also recommended that commercial control products be used for quality control checks.

Assay:
1. Briefly (no longer than 1 second) dip test strip into urine.
2. Ensure that the chemically imprinted pads on the test strip are totally immersed.
3. Draw the edge of the strip along the rim of the specimen container to remove excess urine.
4. Turn the test strip on its side and tap once on a piece of absorbent paper to remove any remaining urine.
5. After the appropriate time, read the test as follows:
   - Hold strip close to color blocks and match carefully, ensuring that the strip is properly oriented to the color chart on the vial label.

All test pads should be read at 1 minute. If Leukocytes pad indicates a trace result, it should be read again at 2 minutes. Color changes that occur after 2 minutes from immersion are not of clinical value. Color changes that occur only along the edge of the test pad should be ignored. Careful removal of excess urine (steps 2 and 3) should eliminate this effect.

Calibration:
Calibration of the Chemstrip 2GP 2LN, 9, 10 with 9SG urine test strips is not required.

Quality Control:
Quality control for this procedure consists of the following laboratory instructions:

1. To verify that the Chemstrip 2GP test strip has not been exposed to heat or moisture, open a new vial of test strips and retest.
2. For further information, contact Roche Diagnostics Technical Service Center, 1-800-428-4674, 7 days a week, 24 hours a day.

Results:
Results are obtained by direct visual comparison with the color scale printed on the vial label by always assigning the value of the nearest color block. No color scale is necessary. The visual color chart is not intended to represent quantitative findings and serve only as a screening mechanism. If quantitative results are desired, it is recommended that further testing of the urine be carried out utilizing a reference procedure.

Limitations:
The test and including interfering substances for each reagent are shown below.

Specific Gravity: Results may vary between urine concentration measuring methodologies due to their differing principles and limitations.

The chemical principle of this test may also cause slightly different results when compared with other urine concentration measuring methods. The test for creatinine, uric acid, ketones, or chlorides, uric acid concentrations greater than 1% may cause a low specific gravity reading relative to other methods. In the presence of moderate amounts of protein (100-500 mg/dl) or ketones, readings tend to be elevated.

pH Test: No known interferences when handled according to instructions.

Leukocyte Test: This test is not affected by erythrocytes in concentrations up to 10,000/µL or by bacteria common in urine. Specimens should not be collected in containers that have been previously used for the collection of blood or blood substitutes.

Glucose: Glucose is oxidized by the enzyme glucose oxidase to produce gluconic acid and hydrogen peroxide from the oxidation of glucose. In turn, a second enzyme, peroxidase, catalyzes the reaction of the hydrogen peroxide with the chromogen tetrazine tetrazolium to form a green dye complex. A positive result is indicated by a color change from yellow to green.

Urobilinogen: Urobilinogen is reacted with 4-methoxyphenylazo-diazonium-tetrafluoroborate in an aqueous medium to form a red azo dye.

Bilirubin: The test for bilirubin is based on the coupling reaction of a diazonium salt with bilirubin in an acidic medium. The application of 2,4-dichlorophenol-naphthylamine-diazonium-tetrafluoroborate, however, which is used in the test strips is unique. This yields a pink to red-orange color proportional to the total bilirubin concentration.

Ketones: The chemical detection of ketones is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the oxygenated peroxide contained in the test pad. Intact erythrocytes hemolyze on the test pad, and the liberated hemoglobin produces a green dot. Since the test pad absorbs several µL of urine, more erythrocytes become visible than would correspond to 1µL.
Urobilinogen Test: The total absence of urobilinogen cannot be detected. Most normal urines give a slight pink reaction. The test gives the same color reaction with urobilinogen as with stercobilinogen; however, the differentiation is not of diagnostic importance. Urine from patients who are being treated with phenazopyridine may show a false-positive reaction. Nitrite concentrations above 5 mg/dL or formalin concentrations above 200 mg/dL (as a preservative) may cause a decrease in the color reaction.

Billybin Test: Large amounts of ascorbic acid present in urine following the ingestion of medication containing vitamin C or fruit juices lower the sensitivity of the test. In case of doubt, the test should be repeated on urine voided at 10 hours after the last administration of vitamin C. Elevated concentrations of nitrite, as in urinary tract infections, may result in lower bilirubin values. Large amounts of urobilinogen in the urine affect the color change of the bilirubin test, but not enough to give a positive result. False-positive readings may be produced by medication that colors the urine red, or which turns red in an acid medium (e.g., phenazopyridine).

Blood Test: False-negative readings are obtained when formalin is used to preserve the urine. Nitrite in excess of 10 mg/dL in the urine (which is rare in urinary-tract infections) delays the reaction. False-positive results can be produced by residues of strongly oxidizing cleaning agents in the urine container. Urine from menstruating females will occasionally yield a positive result. This test has not been found to be affected by the ingestion of reasonable quantities of ascorbic acid.

Expected Values:

**Specific Gravity:** Random urines vary from 1.001–1.055. Twenty-four-hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016–1.022.

**pH:** Urine pH values generally range from 5 to 9 units. The most frequent pH values for the first morning specimens in healthy subjects are between 5 and 6.

**Leukocytes:** Normal leukocytes should produce no color reaction. A "trace" finding indicates a possible borderline situation, and it is recommended that the test be repeated on a fresh urine sample from the same patient. Positive and repeated trace findings indicate the need for further testing of the patient.

**Nitrile:** A concentration as low as 0.05 mg/dL of nitrite will produce a slight pink coloration of the test pad. This indicates a positive result.

**Glucose:** A color change from yellow to light green/green will occur if glucose is present in urine. The concentrations given on the vial label correspond favorably with the albumin concentration in urine. Proteinuria will usually produce persistent values above 30 mg/dL. Clinical significance of the trace result should be determined by additional testing.

**Creatinine:** Due to the test's sensitivity, glucose should not be detected in normal urine. Therefore, any positive reaction should be followed by further diagnostic evaluation of the patient, such as a quantitative blood glucose or glucose tolerance test.

**Ketone:** Ketone bodies should not be detected in normal urine with this test. Fasting or starvation diets may cause positive indications. In known pathological conditions such as diabetes, the presence of ketones may be useful as a marker of metabolic status.

**Urobilinogen:** Concentrations are usually greater in the afternoon than during the remaining part of the day. Values up to 1 mg/dL are usually considered normal.

**Bilirubin:** In normal urine, bilirubin should not be detected with this test. However, this test is very sensitive to bilirubin (0.5 mg/dL) will produce positive results and any positive reaction indicates that further diagnostic evaluation of the patient is needed.

**Blood:** A trace result is equivalent to 5–10 Eryt. Erythrocyte excretion up to 5 Eryt/L may be expected in normal urine.

**Levels above these certainly warrant further diagnostic evaluation of the patient.**

**Performance Characteristics:**

The performance characteristics of the Chemstrip products have been determined both in the laboratory and in clinical tests. For visually read strips, accuracy is a function of the manner in which the color blocks on the vial label are determined and the discrimination of the human eye in reading the tests. Precision is difficult to assess in a test of this type because of the variability in human eye response. It is for this reason that each user is encouraged to develop his own standards for performance.

**Specific Gravity:** The test permits determination of urine specific gravity between 1.000 and 1.050 in steps of 0.005. In general, it correlates within 0.005 with values obtained with refractometric methods. In cases of urine with a pH equal to or greater than 7.0, 0.005 may be added to the specific gravity readings.

**pH:** Values from pH 5 to pH 9 may be read to within 1 unit.

**Leukocytes:** Studies were conducted to compare test pad color development from urines with values obtained by the microscopic method. Clinical testing yielded the following sensitivity and specificity data:

- **n = 200**
- **Sensitivity = 97.2%**
- **Specificity = 99.9%**

**Nitrite:** Up to 100% of all patients with urinary tract infections can be detected by analysis of the first-morning urine specimen. A positive reaction will be detected in 50 to 70% of patients with urinary-tract infections by using a random urine specimen. This is dependent on the number of bacteria, nitrite content and retention time of the urine in the bladder. Prolonged urinary retention in the bladder (4-8 hours) may be necessary to obtain an accurate result. The frequency of false-positive results in normal patients is negligible.

**Inhibition:** In 90% of urines tested, an acetoacetate at 9 mg/dL or acetone at 70 mg/dL will produce a positive reaction. Benthroactyctric acid does not contribute to the color development.

**Urobilinogen:** The sensitivity of the urobilinogen test is approximately 0.4 mg/dL; therefore, most normal urines give a slight pink reaction.

**Bilirubin:** In 90% of tested urines, bilirubin concentrations as low as 0.5 mg/dL are produced.

**Glucose:** Differentiation of hemoglobin from erythrocytes can be determined by the color comparison chart on the vial label. In 90% of urines tested, concentrations of 5 Eryt/L and hemoglobin content corresponding to 10 Eryt/L produce a positive result.

A field study of 637 fresh-frozen urine specimens in routine diagnosis produced no false-negative results and in only a small percentage of cases, recorded a higher erythrocyte concentration than the ten-field sediment method.

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**Bibliography:**

7. Not used.
9. Keaton, A., Abstracts of papers presented at the 126th meeting of the American Chemical Society, p. 31c, Dallas, April, 1956.

This product is covered by the U.S. Patent Nos. 5,064,615; 5,106,532.

**Items Available From Roche Diagnostics:**

- Chemstrip 1D MD urine test strips, 10 tests
- Chemstrip 10 with SG urine test strips, 100 tests
- Chemstrip 8 urine test strips, 100 tests
- Chemstrip 7 urine test strips, 100 tests
- Chemstrip 5 DB urine test strips, 100 tests
- Chemstrip 2 GP urine test strips, 100 tests
- Chemstrip 2 LN urine test strips, 100 tests
- Chemstrip K urine test strips, 100 tests
- Chemstrip K urine test strips, 100 tests

Cat. No. 00513
Cat. No. 00515

**For the Diabetic Patient's Needs:**

- Chemstrip 1K urine test strips, 10 tests
- Chemstrip K urine test strips, 100 tests

Cat. No. 00513
Cat. No. 00515

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