Chemstrip 2 GP, 2 LN, 9, 10 with SG

cobas®

REF **11895397** 160	NDC 50924-145-10	100 tests
REF **11895460** 160	NDC 50924-109-10	100 tests
REF **11895427** 160	NDC 50924-743-10	100 tests
REF **11895362** 160	NDC 50924-152-10	100 tests

Intended use

Urine test strips for specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, blood, and hemoglobin. Chemstrip 2 GP, Chemstrip 2 LN, Chemstrip 9 and Chemstrip 10 with SG urine test strips are intended for use visually.

Summary

Chemstrip urine testing system is a multi-parameter test strip to measure certain constituents in the urine. These measurements are useful in the evaluation of renal, urinary, and metabolic disorders. Chemstrip urine test strips are inert plastic strips to which are attached different reagent pads for determining specific gravity, pH, indication of leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and blood and hemoglobin in urine. *Refer to the outside box and vial label for the specific parameters of the product you are using.* The test pads are uniquely attached to the strip with a nylon mesh which holds the reagent pad in place, protects the pad, and provides for rapid and even wetting of the entire test pad. To prevent urine runover, certain test pads have an inert absorbent paper located between the test pads and the strip.

Chemstrip urine test strips are packaged in a vial with a tightly fitting cap, that contains a drying agent. Each test strip is stable and ready for use when removed from the vial. No additional instrumentation is required.

Test principle

A brief discussion of each test principle follows.

Specific Gravity: In the presence of cations, protons are released by a complexing agent in the test and produce a color change of the indicator bromthymol blue from blue to blue-green to yellow.

pH: The test pad contains the indicators methyl red and bromthymol blue. These give clearly distinguishable colors over the pH range of 5-9. Colors range from orange through yellow and green to blue.[1,2]

Leukocytes: Leukocytes in urine are detected by the action of esterase, present in granulocytic leukocytes, which catalyzes the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a purple color.

Nitrite: Nitrite, if present, reacts with an aromatic amine to give a diazonium salt, which couples with sulfanilamide to yield a red-violet azo dye.[3,4,5]

Protein: The detection of protein is based on the so-called “protein error of pH indicators” (Sörensen, 1909). The indicator used in this test is 3',3",5',5''-tetrachlorophenol-3,4,5,6-tetrabromosulfophthalein. A positive reaction is indicated by a color change from yellow to light green/green.[6,7]

Glucose: Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. In turn, a second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with the chromogen tetramethylbenzidine to form a green dye complex. A positive reaction is indicated by a color change from yellow to green.[8,9]

Ketones: Based on the principle of Legal's test, sodium nitroprusside and glycine react with acetoacetate and acetone in an alkaline medium to form a violet dye complex. A positive result is indicated by a color change from beige to violet.[10,11]

Urobilinogen: Urobilinogen is coupled with 4-methoxybenzene-diazonium-tetrafluoroborate in an acid medium to form a red azo dye.[12]

Bilirubin: The detection of bilirubin is based on the coupling reaction of a diazonium salt (2,6-dichlorobenzene-diazonium-tetrafluoroborate) with bilirubin in an acid medium. The application of 2,6-dichlorobenzene-diazonium-tetrafluoroborate, however, which is used in the test strip is unique. This yields a pink to red-violet color proportional to the total bilirubin concentration.[13]

Blood/Hemoglobin: The chemical detection of blood is based on the strong pseudoperoxidase action of erythrocytes and hemoglobin. Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the organic 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 1 µL.[14,15,16,17,18]

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 green coloration of the test 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.

Precautions and warnings

For in vitro diagnostic use.
Exercise the normal precautions required for handling all laboratory reagents. Disposal of all waste material should be in accordance with local guidelines.

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

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

Storage and stability

Store test strips at 2-30 °C (36-86 °F) . Do not freeze. Chemstrip urine test strips are stable in the original capped vial 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 any freshly voided urine specimen or on urines collected under special conditions, such as first-morning specimens and post-prandial urine. 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 of particular importance 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 immediately refrigerated at 2-8 °C and returned to room temperature before testing. Mix urine thoroughly before testing. Urine should be collected in a container which allows complete immersion of the reagent pads on the test strip. If a cleanly voided urine is not collected, a positive test result for leukocytes or blood may be due to a source of leukocytes or blood external to the renal-urinary system.

Materials provided

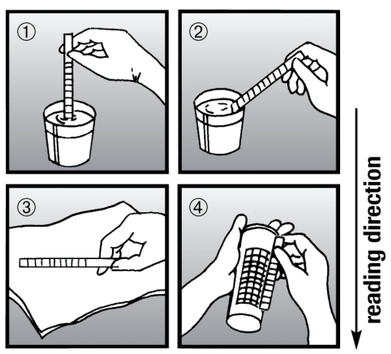
1 vial containing 100 Chemstrip urine test strips. A visual comparison color scale for reading test results is printed on the vial label.

Materials 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 the urine. Ensure that the chemically impregnated pads on the test strip are totally immersed.
2. Draw the edge of the strip along the rim of the specimen container to remove excess urine.
3. Turn the test strip on its side and press against a piece of absorbent paper to remove any remaining urine.
4. 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 the 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 Chemstrip 2 GP, 2 LN, 9 and 10 with SG urine test strips by the user is not required for visual use.

Quality control

Quality control for this procedure consists of following good laboratory techniques and ensuring that reagents have been properly stored and specimens handled according to instructions. The operator should be aware of the sources of error outlined under *Limitations.* Each laboratory should establish its own goals for adequate standards of performance. Commercially prepared control solutions should be used on a regular basis, as established by the institution’s quality control protocols. If the expected results are not obtained and repetition of the assay excludes errors in technique, the following steps should be taken:

1. Check the expiration date stamped on the vial label.
2. To verify that the Chemstrip urine test strips have not been exposed to heat extremes or moisture, open a new vial of test strips and retest.
3. For further information, contact Roche Diagnostics Technical Service Center, 1-800-428-4674, 7 days a week, 24 hours a day, 365 days a year.

Results

Results are obtained by direct visual comparison with the color scale printed on the vial label label by always assigning the value of the nearest color block. No calculations are necessary. The visual color chart is not intended to represent quantitative findings and serves 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 - interference

The limitations 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.[19] The chemical principle of this test may also cause slightly different results compared with other urine concentration measuring methods when elevated amounts of certain urine constituents are present. Glucose and urea 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 ketoacidosis, 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 cleaned with strong oxidizing agents. Do not use preservatives. The drugs cephalexin and gentamicin have been found to interfere with this test. In addition nitrofurantoin colors the urine and this effect interferes with visual interpretation of the test strip. High levels of albumin (≥ 500 mg/dL) in the urine and urinary glucose excretion in excess of 1 g/dL may interfere with the test results. Studies show that formaldehyde (stabilizer) and medication with imipenem, meropenem and clavulanic acid may cause false-positive reactions.[20]

Nitrite Test: Large amounts of ascorbic acid (see under glucose) decrease the sensitivity of the test. False-positive readings may be produced by medication that colors the urine red or which turns red in an acid medium (e.g. phenazopyridine).

Protein Test: False-positive results may be found in strongly basic urine (pH 9 or higher), during therapy with phenazopyridine, when infusions of polyvinylpyrrolidone (blood substitutes) are administered, and when residues of disinfectants containing quaternary ammonium groups or chlorohexidine are present in the urine container.

Glucose Test: The effect of ascorbic acid (vitamin C) retained in the urine due to ingestion of vitamin tablets, antibiotics or fruit juices has been eliminated at glucose concentrations of 100 mg/dL and above so that false-negative readings may only rarely occur, even at high concentration of ascorbic acid. False-positive readings may be produced by strong oxidizing cleaning agents in the urine container.

Ketone Test: Phenylketone or phthalein compounds that may be administered for liver and kidney function tests can produce red-orange to red color shades, which are, however, readily distinguished from the colors obtained with ketone bodies. 2-Mercaptoethane sulfonate sodium (MESNA) or other sulfhydryl-containing compounds may cause false-positive results.[21]

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.

Bilirubin 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 least 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/Hemoglobin 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.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

Expected values

Specific Gravity: Random urines vary from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022.[19]

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 pH 5 and 6.

Leukocytes: Normal urines 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 and/ or urine sample in accordance with the medically accepted procedures for pyuria.

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

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

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

Ketones: 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 an index of metabolic status.

Urobilinogen: Concentrations are usually greater in the afternoon than during the remainder of the day. Values up to 1 mg/dL are usually considered normal.[12]

Bilirubin: In normal urine, bilirubin should not be detectable. 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/Hemoglobin: A trace result is equivalent to 5-10 Ery/µL. Erythrocyte excretion up to 5 Ery/µL may be expected in normal urine.[16,17] Levels above this certainly warrant further diagnostic evaluation of the patient.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Performance characteristics

The performance characteristics of 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 of the human eye. 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 1.030 in steps of 0.005. In general, it correlates within 0.005 with values obtained with refractometric methods. In case of urines 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 = 203

Sensitivity = 97.2 %

Specificity = 90.1 %

Nitrite: Up to 90 % of all patients with urinary tract infections can be detected by analysis of the first-morning urine specimen.[22] A positive result will be detected in 50 to 70 % of patients with urinary tract infections by use of 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 (less than 1 %).

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Protein: In 90 % of urines tested, albumin concentrations of 6 mg/dL or greater produced a color change. The test pad is more sensitive to albumin than globulin, Bence-Jones proteins and mucoproteins.

Glucose: In 90 % of urines tested, glucose concentrations of 40 mg/dL or greater produced a positive result. Sugars other than glucose that may be found in urine were tested and found not to react with the reagent. Reducing substances will not give positive results.

Ketones: In 90 % of urines tested, acetoacetate at 9 mg/dL or acetone at 70 mg/dL will produce a positive reaction. Beta-hydroxybutyric acid does not contribute to the color development.

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

Bilirubin: In 90 % of urines tested, bilirubin concentrations as low as 0.5 mg/dL produced a positive result.

Blood/Hemoglobin: 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 Ery/µL and hemoglobin content corresponding to 10 Ery/µL produced a positive result.[17,18] A field study of 637 freshly voided 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.[16]

Items available from Roche Diagnostics

Chemstrip 10 MD urine test strips, 100 tests	REF 03260763160
Chemstrip 10 with SG urine test strips, 100 tests	REF 11895362160
Chemstrip 9 urine test strips, 100 tests	REF 11895427160
Chemstrip 7 urine test strips, 100 tests	REF 11008552160
Chemstrip 5 OB urine test strips, 100 tests	REF 11893467160
Chemstrip 2 GP urine test strips, 100 tests	REF 11895397160
Chemstrip 2 LN urine test strips, 100 tests	REF 11895460160

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