Chemstrip 5 OB, 7

cobas®

REF **11893467** 160	NDC 50924-467-06	100 tests
REF **11008552** 160	NDC 50924-218-07	100 tests

Intended use

Urine test strips for pH, leukocytes, nitrite, protein, glucose, ketones, blood, and hemoglobin. Chemstrip 5 OB and Chemstrip 7 urine test strips are intended for use visually or on the Roche Diagnostics Urisys 1100 Urine Analyzer.

Summary

Chemstrip urine test strips are a multi-parameter test strips that measure certain constituents in the urine. These measurements are useful in the evaluation of renal, urinary, and metabolic disorders. Chemstrip 5 OB and Chemstrip 7 urine test strips are inert plastic strips to which are attached different reagent pads for determining pH, indication of leukocytes, nitrite, protein, glucose, ketones, 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.

Test principle

A brief discussion of each test principle follows.

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.” 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: The ketone test used in this test pad is based on the reaction of sodium nitroprusside and glycine 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]

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.[12,13,14,15,16]

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 wtih 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. 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

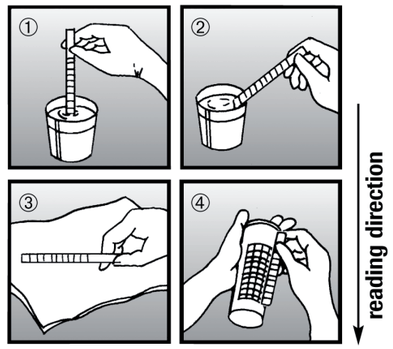
1 vial containing 100 Chemstrip urine test strips. A visual comparison color scale for reading test results is printed on the vial label.

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.

Any color changes appearing only along the edges of the test areas, or developing after more than 2 minutes, do not have any diagnostic significance.

Careful removal of excess urine (steps 2 and 3) should eliminate this effect.

Calibration

Calibration of Chemstrip 5 OB and Chemstrip 7 urine test strips by the user is not required.

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 5 OB, 7 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

For the Urisys 1100 Urine Analyzers: Refer to the operator’s manual regarding results from the analyzer.

For Visual Use: 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.

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.[17]

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, readily distinguished from the colors obtained with ketone bodies. 2-Mercaptoethane sulfonate sodium (MESNA) or other sulfhydryl-containing compounds may cause false-positive results.[18]

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

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 urine 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.

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.[14,15] 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 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.

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.[19] 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 %).

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.

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.[15,16] 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.[14]

Sensitivity Summary: The following table summarizes the sensitivity data obtained with the Urisys 1100 Urine Analyzer. This table lists the level of analyte that is generally detectable as positive when tested with a contrived urine pool. Because of inherent variability in clinical urines, lower levels may be detected under certain conditions.

Reagent Pad	Urisys 1100 Analyzer	Unit
Blood	5 – 20	Ery/µL
Glucose	30 – 40	mg/dL
Ketone (acetoacetic acid)	5 – 15	mg/dL
Leukocytes	30 – 35	Leu/µL
Nitrite	0.06 – 0.10	mg/dL
Protein	25 – 32	mg/dL

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

References

1 Kolthoff I. Acid-Base Indicators. McMillan Co., New York, 1937;171.

2 Free H, Collins G, Free A. Triple-test strip for urinary glucose, protein and pH.

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Clin Chem. 1960;6:352.

3 Griess P. Notes on the paper of Weselsky and Benedikt. Some Azo Compounds. Ber Dtsch Chem Ges. 1879;12:426.

4 Weltmann O. Method for the simple detection of urinary tract infections. Wien Med Wschr. 1922;72:618.

5 Fuchs T, Gutensohn G . Value and limitation of the nitrite test in diagnosis of pyelonephritis. Dtsch Med J. 1967;10:343.

6 Sörensen S. The measurement of the hydrogen ion concentration and its importance for enzymatic processes. Biochem Z. 1909;21:131.

7 Gyure WL. Comparison of several methods for semiquantitative determination of urinary protein. Clin Chem. 1977;23:876.

8 Keston A. Abstracts of papers presented at the 129th meeting of the American Chemical Society, p. 31c. Dallas, April, 1956.

9 Comer J. Semiquantitative specific test paper for glucose in urine. Anal Chem. 1956;28:1748.

10 Legal E. A new acetone reaction and its applicability for the examination of urine. Chem Centr. 1883;14:652.

11 Chertack M, Sherrick J. Evaluation of a nitroprusside dip test for ketone bodies. JAMA. 1958;167:1621.

12 Cook M, Free H, Free A. The detection of blood in urine. Am J Med Tech. 1956;22:218.

13 Leonards J. Simple test for hematuria compared with established tests. JAMA. 1962;179:807.

14 Braun J, Straube W. A new rapid test for diagnosing microhematuria, compared with results of microscopic examination. Dtsch Med Wschr. 1975;100:87.

15 Kutter D, van Oudheusden A, Hivers A, et al. Usefulness of a new test strip for the detection of erythrocytes and hemoglobin in urine. Dtsch Med Wschr. 1974;99:2332.

16 Brühl P, et al. Clinical experience gained with a test strip used to screen for erythrocytes and hemoglobinuria. Therapiewoche. 1976;26:5193.

17 Beer JH, Vogt A, Neftel K, et al. False positive results for leucocytes in urine dipstick test with common antibiotics. BMJ 1996; 313:25.

18 Csako G. False positive results for ketone with the drug mesna and other free-sulfhydryl compounds, Clin Chem. 1987;33/ 2:289.

19 Czerwinski AW, Wilkerson R, Merrill J, et al. Further evaluation of the Griess test to detect significant bacteriuria. Amer. J. Obstet. Gynec. 1971; 10:677.

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