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

Cobas

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

Intended uses
Urine tests for specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, bilirubin, blood, and hemoglobin. Chemstrip 2 GP, 2 LN, Chemstrip 9 and Chemstrip 10 in 8G 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 a number of conditions. Test strips are short plastic strips to which are attached different reagent pads for determining specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, bilirubin, blood, and hemoglobin in urine. Refer to the outside box and inside pad label for the complete list of contents. These pads are uniquely attached to the strip with a nylon mesh which holds the reagent pad in place, processes 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, which contains a drying agent. Each test strip is stable and ready for use when removed from the vial. No additional instrument is required.

Test principle
A brief discussion of each test principle follows.

Specific Gravity: In the presence of cations, proteins are released by a chemical reaction. The test strip and produce color changes that correspond to the specific gravity of the sample.

pH: The pH test is based on the color change of the indicator bromthymol blue from blue to blue-green to yellow.

Protein: The detection of protein is based on the so-called “protein error of pH indicators” (Bornemisza, 1909). The indicator used in this test is 3,3’ 5,5’ tetramethylbenzidineeturazolium in an acid medium to produce a purple color. A positive reaction is indicated by a color change from yellow to light green to green.

Leukocytes: The detection of leukocytes is based on the enzymatic glucose oxidase/peroxidase (GOPOD) method. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of glucose and hydrogen peroxide from glucose, a second enzyme, peroxidase, catalyzes the oxidation 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 to blue.

Ketones: Based on the principle of Legal’s test, sodium nitrate and glycine react with acetoacetic acid 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.

Urobilinogen: Urobilinogen is couched with potassium bromide. 2-Mercapto-ethane sulfonic acid (MESNA) or other sulfur-containing compounds may cause false-positive test results.

Calibration
Calibration of Chemstrip 2 GP, 2 LN, 9, 10 and 10 with SG urine test strips by the user is not required for visual use.

Quality control
Quality control procedure for this product consists of following good laboratory techniques and ensuring that reagents and stored and handled according to the manufacturer’s guidelines. The test is outlined under Limitations. Each laboratory should establish its own guidelines for adequate standards of performance. Commercially prepared control solutions should be used on a regular basis as established by the manufacturer’s quality control protocols. If the expected results are not obtained and repeated testing of the test strip is not successful, 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 or cold, they shall be stored at controlled conditions.
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 by always assigning the value of the nearest color block. No instrument is recommended to represent the results. Positive results are determined by visual examination when comparing qualitative findings and serves only as a screening mechanism. If quantitative methods are used, 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 due to urine concentration measuring methodologies due to their differing principles and limitations. The chemical principle of this test may also cause slight different results compared with other urine concentration measuring methods when elevated amounts of certain urine constituents are present. Glucose and urea concentrations greater than 100 mg/dL may cause slight reading relative to other methods. In the presence of moderate amounts of protein (100-500 mg/dL) or ketochloring, readings tend to be elevated.

pH: Test results may not interfere with the test instructions. Leukocyte: This test is not affected by erythrocytes in concentrations up to 10,000. Results may not be collected if the color in the container is not blood and the urine diluted in excess of 1:10,000. In such cases, the result will not be accepted for the test unless it is found to be in accordance with the medical accepted protocols for pyuria. Nitrage: A concentration as low as 0.06 mg/dL will produce a slight 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 to the albumin concentration in urine. Pathological proteinuria will 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. Results may become positive due to follow up 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 ketotic states, the presence of ketones may be useful as an index of metabolic status.

Urobilinogen: Concentrations are usually greater in the afternoon than during the morning because bacterial oxidation of urobilinogen to urobilin occurs during the night. 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 is an indication that further diagnostic evaluation of the patient should be undertaken.

Blood/Hemoglobin: A trace result is equivalent to 5-10 E/UL. Erythrocupreins (Hb) can cause a positive reaction.

Leukocytes: Above this certain warrant further diagnostic evaluation of the patient. Each laboratory should investigate the transferability of the expected values to its local patient population and if necessary determine its own reference ranges.

Performance characteristics
The performance characteristics of Chemstrip products have been determined by the method described in this technical manual. The test results are a function of the manner in which the color blocks on the vial label are determined, the condition of the vial label, the care taken in reading the test results, and the condition of the urine. It is essential to test the test’s diagnostic performance in urine samples of statistically significant number. This will help to assess in a test of this type because of the variability of the human eye. It is so for the reason that each user is encouraged to develop his own standards for evaluation of this performance characteristic.

Specific Gravity: The test provides determination of urine specific gravity between 1.000 and 1.050. This is without any clinical value obtained with refractometric methods. In case of urine with a pH equal to or greater than 7.0, 0.05 is to be added to the specific gravity readings.

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

n = 203
Sensitivity = 97.2% Specificity = 97.1%
References

8. Keston A. Abstracts of papers presented at the 129th meeting of the American Chemical Society, p. 51c, Dallas, April, 1956.


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