



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" (Sørensen, 1909). The indicator used in this test is 3',3'',5',5''-tetrachlorophenol-3,4,5,6-tetrabromosulphophthalein. 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 μ L of urine, more erythrocytes become visible than would correspond to 1 μ L.^{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

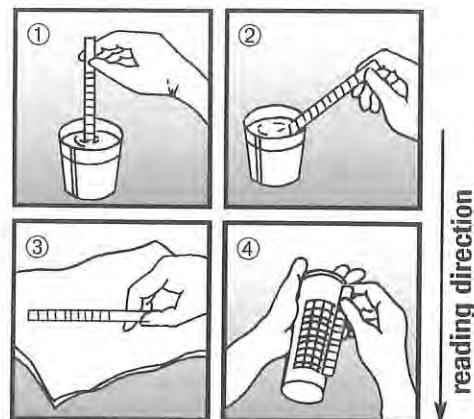
1 vial containing 100 Chemstrip urine test strips. A visual comparison color scale for reading test results is printed on the vial label.

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

- 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.
- Draw the edge of the strip along the rim of the specimen container to remove excess urine.
- Turn the test strip on its side and press against a piece of absorbent paper to remove any remaining urine.
- 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.