UROSTROM

Reagent strips for qualitative testing of Glucose, Protein, pH and Ketone in urine as specified on the label.

BACKGROUND AND SYNOPSIS:

The product insert describes all the tests using UROSTROM Strips. The combination of test parameters is different for each product. Refer the appropriate section relevant to each product, before use.UROSTROM strip is easy to use requires no equipment for testing, simply dip the reagent end of strip in the sample and read the result. This is an easy to use test and can be performed even at home.

PRINCIPLE:

Glucose: Glucose detection with UROSTROM involves GOD/POD a double sequential enzyme reaction. The reaction utilizes glucose oxidase which oxidizes glucose to form gluconic acid and hydrogen peroxidase. Hydrogen peroxide in turn is acted upon by peroxides librating oxygen which oxidizes potassium iodide to liberate iodine.

Protein: Protein test is based on the principle of protein error of indicator. pH indicators like Bromocresol green (BCG) Tetrabromophenol blue (TBH) etc. bind with protein (mainly albumin) and indicate a pH other than the existing pH of the system, which quantitatively (BCG, HABA etc.,) or qualitatively (TBP) corresponds to protein (albumin) concentrations, UROSTROM USES TETRABAROMONPHENOL BLUE WITH GLYCINE buffer.

$_{P}$H: This is based on the principle of double indicator system. Two indicators methyl red and bromo thymol blue are used to give distinct colour changes from orange to green to blue ($_{P}$H 5.0 – 9.0)

Ketone: The acetoacetate and sodium nitroprusside cause reaction in alkaline medium, which produces violet colour.

CLINICAL SIGNIFICANCE:

Glucose:
Glucose (sugar) in urine is one of the most essential laboratory test for many disease conditions and a pretest for all clinics to rule out diabetes and further complications.

Glycosuria may be the first observed sign of diabetes mellitus. Therefore, examination of urine for glucose is part of the basic routine analysis. The appearance of glycosuria in non-diabetics may indicate potential diabetes.

Protein:
Proteinuria is one of the most important indicators of renal disease. Proteinuria may reflect extra renal or intrinsic renal disorders. Marked proteinuria is seen in nephrotic syndrome, in severe cases of glomerularnephritis, nephrosclerosis, amyloid diseases, multiple myeloma etc. Proteinuria is also associated with fever, exposure to heat or cold, excessive exercise and emotional stress.

Ketone:
Diabetes mellitus is the most important disorder in which ketonuria occurs. It also accompanies the other conditions such as anorexia, fasting, starvation fever & prolonged vomiting.

$_{P}$H:
The $_{P}$H of urine is an important indicator of certain metabolic, kidney, gastrointestinal and respiratory factors.

SPECIFICITY & SENSITIVITY:

Glucose: Urostrom strip gives result only when glucose is present in clinically significant concentrations compared to copper reduction test

UROSTROM is more specific and sensitive. It reads positive even as low a concentration of 0.1g/dl of glucose in urine.

Protein: UROSTROM detects as little as 30 mg/dl of protein in urine. The test is more sensitive to albumin than to globulins.

Ketone Urostrom detects as little as 0.5-1.0 mmol/L of Ketone in urine. The test in sensitive to acetoacetic acid.

STORAGE & STABILITY: (Between 15°c to 30°c)

Store in a cool and dry place. Do not refrigerate. Tighten the cap after removing the strip. Do not touch the reagent area of the strip and keep it away from detergents. Do not remove the desiccant bag from the bottle. Once opened, use within 6 months.

SPECIMEN COLLECTION:

UROSTROM can be used for any freshly voided urine sample as first morning, post prandial, or random. If testing is not possible immediately, the specimen should be refrigerated and should be brought back to room temperature before use.

TEST PROCEDURE:

1. Open container & take out a strip. Replace cap immediately.
2. Dip the strip into fresh urine (for not more than 2 seconds.)
3. Remove excess urine by tapping the strip on the rim of the urine container.
   Or. Briefly blot the sides of the strip on the absorbent tissue to remove excess urine.
4. Keep the strip on a horizontal surface for one minute.
5. Compare result with colour chart on the container. Interpolate for the concentration. If required.
   a. In presence of glucose, the original bluish green colour (negative for glucose) changes to green to shades of brown with increasing concentrations, indicating as positive reaction.
   b. In presence of protein the yellow (negative for albumin) changes to yellowish green to dark shades of green to blue (indicating positive result), DEPENDING ON THE CONCENTRATION OF PROTEIN. Compare test area with colour blocks given on the bottle label for respective tests.
   c. In presence of Ketone the original colour (negative for Ketone) changes to shades of pink depending on the amount of ketone, indicating as positive reaction.
   d. The colour range of pH changes from orange shade for pH 5 to shades of yellow green and blue as pH increases.

6 For a qualitative result, the strip should be read between 1-2 minutes after dipping. If positive result is obtained, repeat he test and compare with the colour chart at the specified time. Colour changes beyond two minutes are of no diagnostic value.

7. If necessary, dip a strip in distilled water to use as a reference for negative result.

INTERPRETATION OF RESULT:

GLUCOSE: The colour range of the test is from a negative bluish-green to shades of greenish brown, as the concentration of glucose increases.

PROTEIN: The colour range for protein is from a negative yellow to shades of greenish-yellow to darker shades of green to blue as the concentration of urinary protein increases.

pH: The colour range of pH changes from orange shade for pH 5 to shades of yellow green and blue as pH increases.

KETONE: The colour range of Ketone forms a negative peach colour to shades of pink as the concentration of ketone increases.

LIMITATION OF THE PROCEDURE:

Glucose: A normal health (non-diabetic) individual may excrete glucose in urine up to 150 mg per day (800- 1500 ml urine per 24 hours) given approx. concentration of 5 to 20 mg/dl. But such levels are clinically insignificant. The reagent area is not designed to estimate such low levels. A positive glucose test generally indicates a clinically significant concentration of glucose.

Protein: Normally an amount of protein between 40mg and 80 mg is excreted per 24 hours, but as much as 100 to 150 mg per 24 hours may be considered within normal limits.

KETONE: The reagent strip react as acetoacetic acid in urine. It doesn't do with acetone or β-hydro butyric acid. Normal urine specimens usually conduct negative results in the test. False positive results may occur in highly pigmented urine or those containing large amount of levodopa metabolites.

$_{P}$H: Excessive urine on the test strip may wash the acid buffer from the protein reagent on to the **$_{P}$H** area and cause an error. This is called run over phenomenon.

NOTE:
Concentration of glucose in urine depends on various uncontrollable factors like ambient temperature, RH, patients status with respect to flues intake. Simple quantization of urine glucose and relating it to health status is likely to lead to erroneous conclusions. Hence it is not advisable to correlate urine glucose results to concentrations of glucose in blood or diabetic status of a patient.

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	Attention,see instructions for use		Consult Instructions For Use
IVD	For in vitro diagnostic use only	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number
	Do not use if package is damaged		Date of Manufacturing
	Manufacturer		Use by