

2 PARAMETER URINE TEST STRIPS FOR GLUCOSE & PROTEIN

INTENDED USE

2 Parameter Reagent Strips test for glucose and protein. The strips may be read visually or instrumentally, using the appropriate Urine Chemistry Analyzers such as the Clinitek family of readers. 100 STRIPS PER BOTTLE.

SPECIMEN COLLECTION & PROCEDURE

- 1 Use a fresh urine specimen, less than 4 hours old, and place it into a clean, dry container. Do not centrifuge. Test within one hour. If not possible, refrigerate and restore to room temperature before testing.
- 2 Remove one strip from the bottle and replace the cap tightly immediately. Briefly (no longer than one second) immerse all reagent areas into the specimen. Wipe off excess urine on the rim of the container. Then lightly dab off the residual urine with a piece of tissue paper at the rim of the strip.
- Hold strip in vertical position. Refer to the bottle label for specific reagent areas on the test strip. Compare the test areas with the color scale on the label. Proper reading times are critical for optimal results. See each reagent time as indicated on bottle label. Coloration appearing only along the edges of the test, or developing after more than two minutes, has no diagnostic value. The regent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity. Please refer to bottle label for specific reading time for each reagent.

LIMITATION

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

STORAGE

Do not remove desiccants from the bottle.

Store at temperatures under 30°C (86°F) and out of direct sunlight 2-10°C for longer storage.

Restore to room temperature before use.

Do not use after expiry date. Do not touch any reagent area.

REAGENT AREA INFORMATION (please refer to the ingredients on reverse)

Glucose: The test is specific for glucose; no substance excreted in the urine other than glucose is known to give a positive result. In diluted urine containing less than 0.3mmol/L ascorbic acid, as little as 2.2mmol/L of glucose, may produce a color change that might be

interpreted as positive. If the color appears somewhat mottled at the highest glucose concentrations, match the darkest color to the color blocks. Ascorbic acid concentrations of 3mmol/L or greater and/or high ketone concentrations (4mmol/L) may give false negatives for specimens containing small amounts of glucose (4-7mmol/L). The reactivity of the glucose test decreases as the SG of the urine increase. The reactivity may also vary with temperature. Small amount of glucose are normally excreted by the kidney. These amounts are usually below the sensitivity of this test, but on occasion may produce a color between the "Negative" and the 6mmol/L color blocks, and that is interpreted by the instrument as positive.

Protein: The test area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones protein and mucoprotein; a "Negative" result does not rule out the presence of other proteins. Normally no protein is detectable in urine by conventional methods, although a minute amount is excreted by the normal kidney. A color matching any block greater than "Trace" indicates significant proteinuria. For urine of high specific gravity, highly buffered or alkaline urine, the test area may most closely match the "Trace" color block even though only normal concentrations of protein are present. Further evaluation is needed for "Trace" results. False positive results may be obtained with highly buffered or alkaline urine. Also, false positive results may also be obtained by contamination of the urine specimen with quaternary ammonium compounds or chlorhexidin based disinfectants.

SPECIFIC CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors: the variability of colour perception, specific gravity, pH, and the lighting conditions when the product is read visually. Each colour block or instrumental display value represents a range of values. Because of specimen and reading variability, specimens with analytic concentrations that fall between two levels may give results at either level. Exact agreement between visual results and instrumental results may not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

The following table lists the generally detectable levels of analyses in contrived urine; however, concentrations may be detected under certain conditions:

Reagent Area	Sensitivity	Instrumental range	Visual range
Glucose (Glucose)	4-7mmol/L	0-56mmol/L	0-111mmol/L
Protein (Albumin)	0.15-0.30g/L	0-3.0g/L	0-20.0g/L

INGREDIENTS (100 Strips):

Glucose oxidase	3.50mg
Peroxidase	0.60mg
Potassium iodide	6.50mg
Tetrabromphenol blue	0.30mg
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Exp. Date Please refer to expiry date on the bottle label