

Urinalysis Reagent Strips (10 Parameters)

V20050-60-02

Cat.No:900

INTENDED USE

The Urinalysis Reagent Strips test for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite and leukocytes. The strips may be read visually or instrumentally, using the appropriate Urine Chemistry Analyzers such as the Clinitek family of readers.

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.
- 3 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 reagent 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.

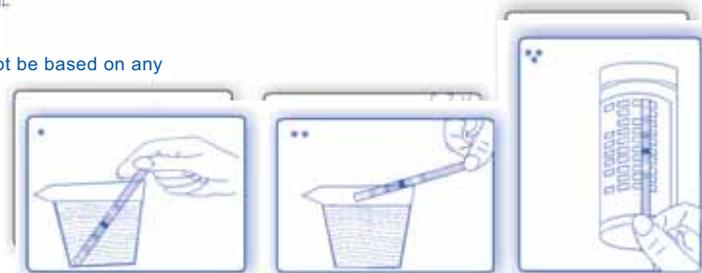
STORAGE

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)

Leukocytes: Normal urine specimens generally yield negative results; positive results are clinically significant. Individually observed "Trace" results may be of questionable clinical significance; however "Trace" results observed repeatedly may be clinically significant. "Positive" results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentration (166mmol/L) or high specific gravity may cause decreased test results. The presence of cephalixin, cephalothin or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity and high levels of the drug may cause a false negative reaction. Nitrofurantoin gives a brown color to the urine that may mask the color reaction on the reagent pad. Any substance that causes abnormal urine color may obscure the color reaction.

Nitrite: This test is specific for nitrite in urine. The test is specific for nitrite and will not react with any other substance normally excreted in the urine. Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test, suggesting the presence of 10^5 or more organisms per ml, but color development is not proportional to the number of bacteria present. A negative result does not prove that there is no significant bacterium. Prolonged urinary retention in bladder (4-8 hours) is essential in order to obtain an accurate result; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the nitrite test is reduced for urine with high specific gravity. Ascorbic acid concentrations of 1.42 mmol/L or greater may cause false negative results with specimens containing small amounts of nitrite ion ($13\mu\text{mol/L}$ or less).

Urobilinogen: This test area will detect urobilinogen as low as $3.3\mu\text{mol/L}$ in urine. A result of $34\mu\text{mol/L}$ represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further. The reagent area may react with substances known to interfere with Ehrlich's reagent, such as p-aminosalicylic acid and sulphonamids. Atypical color reactions may be obtained in the presence of high concentrations of p-aminobenzoic acid. False negative results may be obtained if formalin is present. Highly colored substances, such as azo dyes and riboflavin may mask color development on the test area. Strip reactivity increases with temperature; the optimum temperature is 22-26°C. The absence of urobilinogen cannot be determined with the test.

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.

pH: The pH area measures pH value range of 5-8.5 visually and 5-9 instrumentally. If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur in which the acid buffer from the protein reagent will run onto the pH area, causing a falsely low pH result.

Blood: The significance of the "Trace" reaction may vary among patients, and clinical judgment is required for assessment in each individual case. Development of green spots or green color on the reagent area within 60 seconds indicates the need for further investigation. Blood is often found in the urine of menstruating females. This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The test is equally sensitive to myoglobin as to hemoglobin. Elevated specific gravity or captopril may reduce the reactivity of the blood test. Certain oxidizing contaminants, such as hypochlorite or microbial peroxidase associated with urinary tract infection may result in false positive. Levels of ascorbic acid normally found in urine do not interfere with this test.

Specific Gravity: This test reflects the ion concentration of urine and correlates well with the refractometric method. If pH is equal to or greater than 6.5, then add 0.005 to SG obtained. Instrumental readings are automatically adjusted for pH by the instrument. The test is affected neither by certain nonionic urine constituents such as glucose nor by the presence of radiopaque dye. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (1-7.5g/L) of protein.

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Ketones: The test reacts with acetoacetic acid in urine. It does not react with acetone or B-hydroxybutyric acid. Some high specific gravity/low pH urine may give reactions up to and including "Trace". Clinical judgement is needed to determine "Trace" results. Normal urine specimens usually yield negative results. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketone may appear in the urine in large amounts before serum ketone is elevated. False positive results (Trace) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as Mesna that contain sulphhydryl groups may cause false positive results or an atypical color reaction.

Bilirubin: Normally no bilirubin is detected in the urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction. These colors may indicate the urine specimen should be tested further. Indican (indoxyl sulfate) can produce a yellow-orange to red color response which may interfere with the bilirubin reading. Ascorbic acid concentrations of 1.4 mmol/L or greater may cause false negatives.

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.

SPECIFIC CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors: the variability of color perception, specific gravity, pH, and the lighting conditions when the product is read visually. Each color 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
Bilirubin (Bilirubin)	7-14 mol/L	0-100 mol/L	0-100 mol/L
Ketone (Acetoacetic acid)	0.5-1.0mmol/L	0-8mmol/L	0-16mmol/L
Blood (Hemoglobin Or Red Cell)	105-450 g/L 5-15cells/ L	0-200cells/ L	0-200cells/ L
Protein (Albumin)	0.15-0.30g/L	0-3.0g/L	0-20.0g/L
Urobilinogen (Urobilinogen)	3.3-16 mol/L	3.3-131 mol/L	3.3-131 mol/L
Nitrite (Nitrite ion)	13-22 mol/L	~+~	~+~
Leukocytes (White Cell)	5-15cells/ μ L	0-500cells/ L	0-500cells/ L
pH	N/A	5.0-9.0	5.0-8.5
Specific Gravity	N/A	1.005-1.030	1.000-1.030

INGREDIENTS (100 Strips):

Glucose	Glucose oxidase	3.50mg
	Peroxidase	0.60mg
	Potassium iodide	6.50mg
Bilirubin	2,4-Dichloroaniline diazonium salt	2.20mg
Ketone	Sodium nitroprusside	25.0mg
Specific Gravity	Bromothymol blue	0.30mg
	Poly (methyl vinyl ether maleic acid sodium salt)	15.0mg
pH	Methyl red	0.05mg
	Bromothymol blue	1.00mg
Blood	Isopropylbenzene hydroperoxide	18.0mg
	3,3'-Dimethylbenzidine	5.50mg
Protein	Tetrabromphenol blue	0.30mg
Urobilinogen	p-Dimethylaminobenzaldehyde	1.50mg
Nitrite	p-Arsanilic acid	6.80mg
	N- (1-Naphthyl) Ethylenediamine	2.40mg
Leukocytes	3-Indoly-phenol ester	6.00mg
	Benzendiazonium salt	0.40mg

Exp. Date Please refer to expiry date on the bottle label