

Collect fresh urine in a clean container and test it as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately and let it return to room temperature before testing. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resulting changes in pH and bacterial consumption of urine glucose. A shift to alkaline pH may cause false results with the protein test area.

PROCEDURE :

MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS

1. Collect random urine specimen in a clean dry container. Mix well immediately before testing.
2. Remove the required strip/s from the bottle and replace the cap immediately. Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.
3. While removing the strip, run the edge against rim of the urine container to remove excess urine. Hold the strip in horizontal position to prevent possible mixing of chemicals from adjacent reagent areas.
4. Compare reagent areas to corresponding colour chart on the bottle label at the time specified.

HOLD THE STRIP CLOSE TO COLOUR BLOCKS AND MATCH CAREFULLY.

NOTE : The colour chart should be matched under good light (but not under direct sunlight). Proper incubation time is critical for optimal results. Read the Glucose test at 30 seconds and protein at 60 seconds after dipping. Colour changes that occur after two minutes are of no diagnostic value.

EXPECTED VALUES :

GLUCOSE : Normally no glucose is detectable in the urine, although a minute amount is excreted by the normal kidney. A slight green colour which is less than trace is insignificant.

PROTEIN : Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. However, any colour change which is less than trace colour is insignificant.

Reagents and Performance Characteristics : Read on the dry weight at the time of impregnation, the concentrations given may vary within manufacturing tolerances. The following table below indicates read times and performance characteristics for each parameter.

REAGENT	READTIME	COMPOSITION	DESCRIPTION
Glucose (Glu)	30 Seconds	1.5% w/w glucose oxidase; 0.5% w/w peroxidase; 10.0% w/w potassium iodide; 75.0% non-reactive ingredients	Detects glucose as low as 50-100 mg/dl (2.5-5 mmol/L).
Protein (PRO)	60 Seconds	0.3%w/w tetrabromophenol blue; 99.7% w/w buffer and non-reactive ingredients	Detects albumin as low as 7.5-20 mg/dL (0.075-0.2g/L)

The performance characteristics of the Urinalysis Reagent Strips (Urine) have been determined in both laboratory and clinical tests parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed, Please refer to the Limitations section in this package insert.

Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color block on the chart corresponds to a range of analyte concentrations.

Glucose : This test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose, nor reducing metabolites of drugs; e.g. salicylates and nalidixic acid. This test may be used to determine whether the reducing substance found in urine is glucose. Approximately 100mg/dl glucose in the urine is detectable.

Protein : The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones proteins and mucoprotein; a negative result does not rule out the presence of these other proteins. The test area is sensitive to 15mg/dl albumin. Depending on the inherent variability in clinical urine lesser concentration may be detected under certain conditions.

LIMITATIONS OF THE PROCEDURE :

GLUCOSE : High specific gravity in combination with high pH may reduce sensitivity of the test resulting in a false negative at low concentration of glucose. Ascorbic acid concentration of 50 mg/dl or greater may cause false negative results for specimens containing small amount of Glucose. Ketone bodies reduce the sensitivity of the test.

PROTEIN : False positive results may be obtained with highly buffered or alkaline urines. Contamination of the specimen with quaternary ammonium compounds or with skin cleaners containing chlorhexidine may also produce false positive results. The protein area is more sensitive to albumin, than to globulins, haemoglobin, Bence - Jones protein and mucoprotein. A negative result does not rule out the presence of these other proteins.

REFERENCES

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EN 980:2008 (E) MEDICAL DEVICES SYMBOL			
	Temperature Limitation		Date of Manufacture
	In vitro Diagnostic Device		Company name & address
	Batch Code		Company Name
	Refer Operating Instructions		Authorised Representative in European Community
	Use by		Sufficient for
	Do Not Reuse		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE
	CONTROL -		NEGATIVE CONTROL
	CONTROL +		POSITIVE CONTROL
Authorised Representative in EC			

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