URINE GLUCOSE / PROTEIN TEST STRIP

BHAT Bio-Scan®

For Professional Use

IVD

A rapid test for the semi quantitative determination for the presence and concentration of glucose and protein in urine.

Read the pack Insert before use provided along with the kit

REF UGPS

INTENDED USE :Urine glucose protein test is a rapid test for the semi quantitative determination for the presence and concentration of glucose and protein in urine.

INTRODUCTION :

Glucose / Protein Strips are firm plastic strips to which glucose and protein reagent areas are affixed. The strips provide a semi-quantitative determination for the presence and concentration of glucose and protein in urine. The reagent test areas on the strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The strips may be read visually requiring no additional laboratory equipment for testing. To begin optimal results, it is necessary to use FRESH well mixed un-centrlfuged urine.

CHEMICAL PRINCIPLES OF THE PROCEDURE :

GLUCOSE :

The test is based on a double sequential enzyme reaction. One enzyme glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidise the chromogen to colours ranging from green to brown.

PROTEIN :

The test is based on the protein - “error-of indicators” principle.At a constant pH, the development of any green colour is due to the presence of protein. The colors range from yellow for ‘negative through yellow-green and green to blue for positive’ reactions.

STORAGE :

Store at room temperature (15 to 30º C) and out of direct sunlight . Do not store in a refrigerator. Do not use after the expiry date.

PACK SIZE : Available in Packs of 50 and 100 Tests.

CONTENSTS OF KIT : Testing devices and silicagel as a dehydrant & Pack Insert.

MATERIAL REQUIRED BUT NOT PROVIDED : Urine Container

WARNING AND PRECAUTIONS :

1.Remove the strip/s for immediate use only.
Replace the cap promptly and tightly after removing the reagent strip.
2.Do not transfer the strips from their original bottle to any other bottle.
3. Do not remove the desiccant from the bottle.
4. Care must be taken not to touch the test reagent areas of unused strips.
5. Protect reagent strips from moisture, to prevent deterioration during storage.
6. Avoid contamination with hydrogen peroxide or any strong oxidising agent, such as hypochlorite.
7. Do not combine strips with different lot numbers together.
8. All reagent strips must be used within three months from the date of opening the bottle.
9. The strips are for in vitro diagnostic use only.

SPECIMEN : Fresh Urine

SPECIMEN COLLECTION AND PREPARATION :

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 i t return to room temperature before testing. Prolonged exposure of un preserved urine to room temperature may result in microbial proliferation with resulting changes in pH and bacter-ial 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 CARE FULLY.
NOTE : The color 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 60 seconds and protein at 60 seconds af ter dipping. Color changes that occur after two minutes are of no diagnostic value.

EXPECTED VALUES :

GLUCOSE : Normal ly 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 characteri stics for each parameter.

REAGENT	READTIME	COMPOSITION	DESCRIPTION
Glucose (Glu)	60 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 Urinalys is 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. salicyclates 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 quartenary 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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3. Shchersten B, Fritz H. Subnormal Levels of Glucose in Urine. JAMA 201:129-132 1967.
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BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL

30C 15C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL –	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

R-10, 07-05-2013

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