

# URINE GLUCOSE - KETONE TEST STRIP



For Professional Use

**A Rapid Test for the Semiquantitative determination for the presence and concentration of Glucose & Ketone in Urine**



Read the pack insert before use provided along with the kit

UGKS

**INTENDED USE :** Urine glucose ketone test is a rapid test for the semiquantitative determination for the presence and concentration of glucose and ketone in urine.

**INTRODUCTION :** Glucose / ketone Strips are firm plastic strips to which glucose and ketone reagent areas are affixed. The strips provide a semi-quantitative determination for the presence and concentration of glucose and ketone 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-centrifuged 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 colors ranging from green to brown.

#### KETONE :

The test is based on the reaction of acetoacetic acid in the urine with nitroprusside. The resulting color ranges from buff-pink for a negative reaction to purple for positive reaction.

#### STORAGE :

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

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

#### CONTENTS OF KIT

Pack Size	50T	100T
Test Strip	50 Nos.	100 Nos.
Silicagel	1 No.	1 No.
Pack Insert	1 No.	1 No.

#### 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 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 color chart on the bottle label at the time specified.

**HOLD THE STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY.**

**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 Ketone at 40 seconds after dipping. Color 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 color which is less than trace is insignificant.

**KETONE :** Normally no ketone are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy & frequent strenuous exercise.

**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)	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).
Ketone (KET)	40 Seconds	5% w/w sodium nitroprusside; 95% w/w buffer	Detects acetoacetic as low as 2.5-5 mg/dL (0.25-05.mmol/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. 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.

**Ketone** : The ketone test area provides semi quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone. The reagent area detects 5-10mg/dL acetoacetic acid in urine.

#### 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.

**KETONE** : Normal urine specimens yield negative results with this reagent. False positive results may occur with highly pigmented urine, specimen or those containing larger amount of levodopa metabolites.

#### REFERENCES

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4. McGarry Jd, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517- 523 May, 1978.
5. Williamson DH. Physiological Ketoses, or why Ketone Bodies? Postgrad. Med J. (June Suppl.): 372- 375, 1971.
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9. Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry 2nd Ed. 2205, 1994.
10. Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.

**NOTE::** Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

#### LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application thereof.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
	Temperature Limitation		Date of Manufacture		In vitro Diagnostic Device
	Batch Code		Company name & address		Consult Instructions For Use
	Use by		Company Name		Authorised Representative in European Community
	Do Not Reuse		Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE		NEGATIVE CONTROL
	CONTROL		POSITIVE CONTROL		



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