

pH : The pH test area permits quantitative differentiation of pH values to one unit within the range of 5-9. pH reading are not affected by variation in the urinary buffer concentration.

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.

REFERENCES

- Free AH, Free HM. Urinalysis, Critical Discipline of Clinical Science. CRC Crit. j Rev. Clin. Lab. Sci. 3(4): 481-531, 1972.
- Yoder J, Adams EC, Free, AH. Simultaneous Screening for Urinary Occult Blood, Protein, Glucose and PH. Amer. J. MedTech. 31:285, 1965.
- Shchersten B, Fritz H. Subnormal Levels of Glucose in Urine. JAMA 201:129-132 1967.
- McGarry Jd, Lilly. Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, 1978.
- Williamson DH. Physiological Ketoses, or why Ketone Bodies? Postgrad. Med J. (June Suppl.): 372-375, 1971.
- Paterson P, et al. Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865; April 22, 1967.
- Fraser J, et al. Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. clin. Chem. Acta II: 372-378, 1965.
- Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 18th Ed. Philadelphia. Saunders. 396-397, 415, 1991.
- Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry 2nd Ed. 2205, 1994.
- Tietz NW. Clinical Guide to Laboratory Tests. W.B. Saunders Company. 1976.

EN 980:2008 (E) MEDICAL DEVICES SYMBOL

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	Temperature Limitation		Date of Manufacture		In vitro Diagnostic Device
	Batch Code		Company name & address		Refer Operating Instructions
	Use by		Company Name		Authorised Representative in European Community
	Do Not Reuse		Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE		NEGATIVE CONTROL
	POSITIVE CONTROL				

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Authorised Representative in EC _____



URINE GLUCOSE-KETONE-SPECIFIC GRAVITY-pH-PROTEIN TEST STRIPS

A rapid test for the semiquantitative determination for the presence and concentration of Glucose, Ketone, Specific gravity, pH and Protein in urine.

For Professional Use



READ THIS PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

Catalogue No. : UGKSP

Intended Use : Urine Glucose Ketone Sp. Gravity pH protein test is a rapid test for the semiquantitative determination for the presence and concentration of Glucose, Ketone, Specific gravity, pH and Protein in urine.

Introduction : Urine Glucose Ketone Sp. Gravity pH protein reagent strips are firm plastic strips to which Glucose, Ketone, Specific gravity, pH and Protein reagent areas are affixed. The strips provide a semiquantitative determination for the presence and concentration of Glucose, Ketone, Specific gravity, pH and Protein in urine.

Chemical Principles of the Procedure :

GLUCOSE : This 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.

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

SPECIFIC GRAVITY : This test is based on the apparent pKa change of certain pretreated poly electrolytes in relations to ionic concentration. In the presence of an indicator, colours range from deep blue - green in urines of low ionic concentration through green and yellow - green in urines of increasing ionic concentration.

pH : This test is based on double indicator principle that gives a broad range of colours covering the entire urinary pH range. Colours range from orange through yellow and green to blue.

PROTEIN : This 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 colours range from yellow for 'negative' through yellow-green and green to blue for positive' reactions.

Storage : Store at room temperature (between 15°C-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 the Kit : Testing devices and silicagel as a dehydrant.

Material required but not provided : Urine container.

Warning And Precautions :

- Remove the strip/s for immediate use only. Replace the cap promptly and tightly after removing the reagent strip.
- Do not transfer the strips from their original bottle to any other bottle.
- Do not remove the desiccant from the bottle.
- Care must be taken not to touch the test reagent areas of unused strips.
- 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.
10. For single 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. 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 the 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. The Protein and pH area may be read immediately or at any time upto 1 minute after dipping. **Colour changes that occur after one minute 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.

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

SPECIFIC GRAVITY : Random urine may vary in specific gravity from 1.003 to 1.040 + Twenty four hour urines from normal adult with normal diets and normal fluid intake will have a specific gravity of 1.016 to 1.022.

pH : Normal urine is slightly acidic with a pH of 6 and urine pH values generally range from 5 to 8.

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.

LIMITATIONS OF THE PROCEDURE :

1. **GLUCOSE** : High specific gravity in combination with high pH may reduce sensitivity of the test resulting in a false negative of 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.
2. **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.
3. **SPECIFIC GRAVITY** : The chemical nature of the specific gravity test may cause slightly different results from those obtained with other specific gravity methods when elevated amount of certain urine constituents are present.

Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl) of protein.

4. pH : If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "run over" may occur, in which the acid buffer from the protein reagent will run on to the pH areas, causing a false lowering in the pH result.

5. PROTEIN : False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds or with skin cleansers 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.

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	READ TIME	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)
Ketone (KET)	40 Seconds	5% w/w sodium nitroprusside; 95% w/w buffer	Detects acetoacetic acid as low as 2.5-5 mg/dl (0.25-0.5 mmol/L)
Specific Gravity (SG)	45 Seconds	2.5% w/w bromothymol blue indicator, 17.5% w/w buffer and non-reactive ingredients; 55% poly(methyl vinyl ether/ maleic anhydride); 25% sodium hydroxide	Detects urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within + 0.005
pH	60 Seconds	0.5% w/w methyl red sodium salt, 5% w/w bromothymol blue; 94.5% w/w non reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9
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 - 0.2 g/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 analyze concentrations.

Specificity :

The performance characteristics of Urine Glucose Ketone Sp. Gravity pH Protein reagent strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, Urine Glucose Ketone Sp. Gravity pH Protein reagent strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above.

For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for that users are encouraged to develop their own standards of performance.

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.

Ketone : The ketone test area provides semiquantitative results and reacts with acetoacetic acid in urine. This test does not react with betahydroxybutyric acid or acetone. The reagent area detects low as 5 - 10mg/dl acetoacetic acid in urine.