

URICHA....Urine Test Strips for Urine Analysis
URICHA - GK

(Strips for determination of Glucose & Ketones in Urine)
In vitro diagnostic test kit, for professional use only

INTENDED USE :

Screening test for detection of Glucose and Ketones in urine which may indicate diabetes, metabolic abnormalities, URICHA - GK Test strips should be used for visual readings only.

ORDERING INFORMATION :	Pack Size	Cat No.
	1 X 50 Test Strips	UR GK 01 50
	1 X 100 Test Strips	UR GK 01 100
	6 X 100 Test Strips	UR GK 06 100

INSTRUCTIONS FOR USE :

Please make sure that the test sample is at Room Temperature. Dip the test strip for approximately two second into the urine. Draw it across the rim of the container to remove excess urine, as well as by gently tapping the side of strip on tissue paper. Compare colour changes with the colour chart on the bottle label between 60-90 seconds. Colour changes that take place after 90 sec. are of no significance. The urine sample to be tested should not be older than 2 hours. The results obtained with Uricha GK correspond to the concentration ranges indicated on the colour chart.

REAGENT :

Glucose :		Ketones:	
Glucose Oxidase	1.7 %	Sodium Nitroprusside	4 to 5%
Peroxidase	0.2 %		
Preservatives	0.1 to 1.0%		

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

Store the container between 15 to 30°C in a dry place. The test strips are stable, when stored properly up to the date of expiry indicated on vial label.

WASTE MANAGEMENT :

Please dispose all used Test Strips in accordance with your local laws and regulations.

WARNINGS & PRECAUTIONS :

In any case, in order to establish a final diagnosis and prescribe an appropriate therapy, the results obtained with test strips should be correlated with other medical results. The effect of medicaments or their metabolic products on the test is not known in all cases. In case of doubt it is recommended not to take the medicaments and repeat the test. Use well washed and clean containers only for urine collection. The presence of usual urine preservatives will not affect the test results. Remove only as many test strips as required, and reseal the container immediately after use. Do not touch the test pads. Avoid exposing the strips to sunlight and moisture.

The pack contains a non-poisonous and harmless desiccant. In case this desiccant is swallowed accidentally, then drink plenty of water, seek medical aid.

SPECIMEN :

Use fresh and uncentrifuged urine.
Shake urine sample well before use.

PRINCIPLE :

GLUCOSE : The detection is based on the glucose oxidase-peroxidase-chromogen reaction. Apart from glucose, no other compound in urine is known to give a positive reaction.

KETONES : The test is based on the principle of Legal's test. Acetoacetic acid and acetone form a violet coloured complex with sodium nitroprusside in alkaline medium.

PERFORMANCE CHARACTERISTICS :

Measuring Range / Specificity / Sensitivity / Interpretation

Glucose : Pathological glucose concentrations are indicated by a colour change from green to bluish green. Yellow or greenish test fields should be considered negative or normal. The colour fields correspond to the following ranges of glucose concentrations : neg., Norm. 20 (1.1), Trace 50 (2.8), +150 (8.33), ++500 (28), +++1000 (55) mg/dl (mmol/L). Larger amounts of ascorbic acid which may be present in urine after a high intake of vitamin C (e.g. vitamin tablets, antibiotics or fruit juices) can lead to lower or falsely negative results. In addition an inhibitory effect is produced by gentisic acid. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents.

Ketones : The test is more sensitive to acetoacetic acid than to acetone. Values of 10 mg/dl acetoacetic acid or 50 mg/dl acetone are indicated. The colour fields correspond to the following acetoacetic acid values : neg., Trace 5 (0.5), +15 (1.5), ++40 (4), +++80 (8), +++++160 (16) mg/dl (mmol/L). Phenylketones in higher concentrations interfere with the test, and will produce variable colours. β-Hydroxybutyric acid is not detected. Phthalein compounds interfere by producing a red colouration.

QUALITY CONTROL :

To ensure adequate quality, use of commercially available urine control is recommended.

BIBLIOGRAPHY :

1. Yoder, J. Adams, E.C., and Free. H.M.: Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH. Amer. J. Med Tech. 31:285; (1956).
2. Shchersten, B. and Friz, H.: Subnormal Levels of Glucose in Urine. JAMA 201:129-132; (1967).
3. Tietz NW. Textbook of Clinical Chemistry W.B. Saunders Company. 1986, 1734.

SYMBOLS USED ON THE LABELS :
