ROBONIK®

URICHA....Urine Test Strips for Urine Analysis

URICHA - GPH

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

INTENDED USE:

Screening test for detection of Glucose, Protein and pH in urine which may indicate diabetes, metabolic abnormalities and diseases of kidney and urinary tract, URICHA - GPH Test strips should be used for visual readings only.

ORDERING INFORMATION:

Pack Size	Cat No.
1 X 50 Test Strips	UR GPH 01 50
1 X 100 Test Strips	UR GPH 01 100
6 X 100 Test Strips	UR GPH 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 30 & 60 seconds. Colour changes that take place after 1 minute are of no significance. When tested the urine should not be older than 2 hours. The results obtained with Uricha GPH correspond to the concentration ranges indicated on the colour chart.

REAGENTS :

Glucose: Glucose Oxidase 1.7 % Peroxidase 0.2 % Preservatives 0.1to1.0%	**Protein:** Tetrabromophenol Blue 0.1to1.0%
	pH: Methyl Red 2.8 µg Bromothymol Blue 10 µg

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.

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 to prescribe an appropriate therapy, the results obtained with test strips should be correlated clinically. 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 accidently, 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.

PROTEIN: The test is based on the "protein error" principle of indicators. The test zone is buffered to a constant pH value and colour changes from yellow to greenish blue in the presence of albumin. Other proteins are indicated with less sensitivity.

pH: The test paper contains indicators which clearly change colour between pH 5 and pH 8.5 (from orange to green to turquoise).

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. (yellow), Trace (greenish), 100, 250, 500 and 1000 mg/dl or neg. (yellow), Trace (greenish), 5.5, 14, 28 and 55 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.

Protein: The minimum sensitivity of the test strip is 10 mg protein/dl urine. The colour fields correspond to the following ranges of albumin concentrations: Negative, Trace, 30, 100, 300 and 500 mg/dl or negative, Trace, 0.3, 1.0, 3.0 and 5.0 g/l Falsely positive results are possible in alkaline urine samples (pH > 9), after infusions with polyvinylpyrrolidone (blood substitute), after intake of medicaments containing quinine and also by disinfectant residues in the urine sampling vessel. The protein colouration may be masked by the presence of medical dyes (e.g. methylene blue) or beetroot pigments.

pH: The pH value of fresh urine of healthy individuals varies between pH 5 and pH 6. The colour scale gives a clear distinction of pH value between pH 5 and pH 8.5.

QUALITY CONTROL:

To ensure adequate quality, use of commercially available urine control is recommended. ROBONIK offers URICHA N & P Control in 2 X 15 ml pack size.

BIBLIOGRAPHY:

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2. 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).

3. Shchersten, B. and Friz, H.: Subnormal Levels of Glucose in Urine. JAMA 201:129-132; (1967).

4. Tietz NW. Taxtbook of Clinical Chemistry W.B. Saunders Company. 1986, 1734.

ROBONIK®
An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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SYMBOLS USED ON THE LABELS:

IVD For in vitro diagnostic use | Store at | Consult Instructions for use | REF Catalogue Number | Exp. Date | LOT Lot No. | Do Not Reuse | Manufacturer's Address | Date of Manufacture | Protect from Direct Sunlight | Protect from Moisture

Ver.: URGP/0513/00