DIAGNOSTIC TEST STRIPS FOR URINALYSIS

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IVD

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Reagent Strips for the rapid determination of Proteins, Ketones (Acetoacetic Acid) and Glucose in urine.

Product name	REF	Σ	Glucose	Ketones	Proteins
Uro-dip 2VGK	URPH0022	100	☐	☐	
Uro-dip 2VPG	URPH0023	100	☐		☐

SUMMARY AND EXPLANATION:
Uro-dip Reagent Strips are dip-and-read test strips for *In Vitro* Diagnostic Use only for testing above items in urine. Test result may provide information regarding the status of carbohydrate metabolism and kidney function.

WARNING AND PRECAUTIONS:
For *in vitro* diagnostic use only. For professional use only.

CHEMICAL PRINCIPLES OF PROCEDURE AND INGREDIENTS:

Protein - The test is based on colour change of acid-base indicator, which is caused by presence of proteins. It is particularly sensitive to albumin, but is much less sensitive to globulin, mucoprotein, haemoglobin and Bence-Jones protein.
Ingredients: tetrabromphenolphtalein ester 0.21 %; tetrabromphenol blue 0.35 %

Ketones - The test is based on the principle of Legal's test and is more susceptible to acetoacetic acid than to acetone. Test does not react with ß-hydroxybutyric acid. The colour scale is calibrated for acetoacetic acid.
Ingredients: sodium nitroprusside 4.9 %

Glucose - The test is based on the specific glucose oxidase/peroxidase reaction and is specific for D-glucose. The reagent pad does not react with other sugars, it reacts with presence of D-glucose by blue-green to brown coloration.
Ingredients: glucose oxidase 7.7 %; peroxidase 2.6 %; potassium iodide 12.4 %

STORAGE AND HANDLING:
Store in a cool, dry place at temperatures between (+2 to +30) °C. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. When stored in a original container, the product is stable up to the expiry date printed on the label. Replace the bottle cap immediately and tightly after removing test strips, and keep the vial tightly closed between tests. Do not touch test areas of urine reagent strips. Do not open container until ready to use. Discoloration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, confirm that the product is within its expiration date and is reacting properly using known negative and positive control materials.

SPECIMEN COLLECTION AND PREPARATION:
Collect urine in a clean, dry container that allows complete immersion of all the fields on the test strip. Do not add preservatives. Test the specimen as soon as possible, with the sample well mixed but not centrifuged. The use of fresh morning urine is recommended for optimal tests. If immediate testing is not possible, the sample should be stored in the refrigerator, but not frozen, and then brought to room temperature before used in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination. Skin cleansers containing chlorhexidine may affect protein test results if specimen contamination occurs.

VISUAL TEST PROCEDURE:

The procedure must be followed exactly to achieve reliable results. Do not divide test strips!

1) Remove only as many test strips as are required, and reseal the tube immediately after use.
2) Do not touch test pads of the strips.
3) Completely immerse all reagents pads in specimen (no longer than 1-2 sec.)
4) Run edge of the strip against rim of urine container to remove excess urine. Hold the strip in horizontal position.
5) Evaluate the result using the comparing with concentration scale on the label.

Notes: For visual evaluation compare the tests pads to the corresponding colour scale on the label after approx. 30 sec.

LIMITATIONS OF PROCEDURE:

Protein - In strongly alkaline urines (pH >8) from patients on medication with quinine or quinoline containing drugs false positive reading may be obtained. False positive results may be found when the urine collection vessel contains traces of disinfectants with quarternary ammonium groups. On the other hand, in the presence of non-ionic or anionic detergents, false-negative results may occur. Do not take the colour of the dry pad into consideration.

Ketones - Drugs and diagnostics on the basis of phenolphtalein or sulphophthalein may turn red to purple because of alkaline reaction of the pad.

Glucose - The reaction is independent on pH. High ketone level (>40 mg/dl) may cause false negative results.

All diagnostics pads do not interfere with the common concentration of the ascorbic acid.

EXPECTED VALUES:

Protein - Normal urine specimens ordinarily contain some protein (< 15 mg/dl).

Ketones - Normal concentration of ketone bodies is lower than 2 mg/dl.

Glucose - Abnormal concentration of glucose in urine is higher than 100 mg/dl.

TEST PAD AND SENSITIVITY (SPECIFICITY):

Protein - 0.15 g/l (15 mg/dl) – albumin

Ketones - 0.1 – 0.2 mmol/l (1.0 – 2.0 mg/dl) - acetoacetic acid

Glucose - 4.2 mmol/l (75 mg/dl) - D-glucose

PLEASE NOTE:
Knowledge of the effects of drugs or their metabolites upon the individual tests is not yet complete. In doubtful cases, it is advisable to repeat the test after discontinuing a drug. The sensitivity depends upon the variability of urines. The semiquantitative analysis is not sufficient for the completing of diagnosis.

QUALITY CONTROL:
URINORM control urines, Cat. No. REG00053 are designed for verification and confirmation of precision and accuracy of Uro-dip 2VGK and Uro-dip 2VPG diagnostic strips as well as Uro-dipcheck 240e and Uro-dipcheck 400e. It is recommended to perform QC measurements according to your local laboratory guidelines. More information about quality control can be found in Uro-dipcheck 240e and Uro-dipcheck 400e user manuals.

STORAGE:
Keep Diagnostic Test Strips in tightly closed original tubes in a dry and dark place at (+2 to +30)°C. The strips must be kept away from moisture, direct sunlight, elevated temperature and chemical fumes in the laboratory. When stored under these conditions, test strips are stable to the expiry date given on the pack.

WASTE DISPOSAL:
Used strip should be treated as potentially infectious and should be liquidated in accordance with local and national regulations relating to the safe handling of such materials. Let waste recycle or put it to municipal waste.

Date of revision: 20. 12. 2022

USED SYMBOLS

IVD In Vitro Diagnostics	REF Catalogue Number
Expiry Date	Storage Temperature
LOT Lot Number	See Instructions for Use
Keep away from Sunlight	Do not reuse

QUALITY SYSTEM CERTIFIED ISO 13485

Erba Lachema s.r.o., Karásek 2219/1d, 621 00 Brno, CZ
e-mail: diagnostics@erbamannheim.com, www.erbamannheim.com

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