Urine Reagents Strips 3 parameters (Urinalysis)

IVD CE

PRODUCT CODE
US001

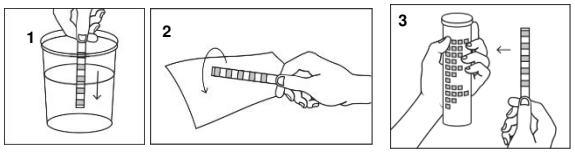
Intended Use
Urine Reagent Strips (US) are used for quick and simultaneous semiquantitative and qualitative screening of multiple urine parameters in one easy testing format. The testing range can be any combination of the following parameters:
Protein, Glucose, pH.

Clinical Significance
Preliminary screening test for diabetes, liver disease, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities during routine examinations, and for use in general preventative medicine.

Specimen Collection
Collect urine in a clean container and test as soon as possible. **Do not centrifuge**. The use of urine preservatives should be avoided. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately at 2°C – 4°C and test within 4 hours. Allow refrigerated urine specimen to return to room temperature (15°C – 25°C) before testing.

Procedure
Before use, ensure that the test strips and container are not damaged, and that the expiry date and maximum storage temperature have not been exceeded. In these cases, the container and test strips must be discarded. Use fresh midstream urine less than 4 hours old. Always collect midstream urine into a clean, dry container, free of detergents.
Remove one strip from the container taking care not to touch the reagent areas. Immediately close the container securely using the original cap.

1. Briefly (one second only) dip all reagent areas into the urine sample.
2. Remove the test strip and **blot the side of the test strip on absorbent paper** to remove excess urine.
3. After 60 seconds, compare the test strip reagent areas with the colour scale on the label (after 60 – 120 seconds for leukocytes).



Proper reading times are critical for optimal results. Coloration appearing along the edges of the test pads or developing after more than two minutes after immersion has no diagnostic value. Visual interpretation should take place in diffuse daylight.

Clinical Use, Test Principles, Expected Values and Limitations

Protein: Intended to detect the presence of protein in the urine. Identification of urinary protein is used in the diagnosis and treatment of renal diseases. The test is based on the "protein error" principle of the indicator. The test is especially sensitive to albumin and less sensitive to other proteins. Normally, no protein is detectable in the urine of healthy individuals. Trace values (for example values between negative and 30 mg/dL) should be reported as negative. False positive results are obtained with urine of high alkalinity, urine with high specific gravity, and urine containing quinine, polyvinylpyrrolidone (PVP), detergents or quaternary ammonium compounds (disinfectant residue in the urine collection vessel). The colour fields correspond to the following values: neg (negative), 30, 100 and 500 mg/dL, or neg (negative), 0.3, 1.0 and 5.0 g/L.
Interpretation: When a result falls between values, read to the lowest colour block. Any "trace values" should be reported as negative.
Detection range: 30 – 500 mg/dL (0.3 – 5.0 g/L).

Glucose: Intended to measure glucose (glucosuria) in urine. Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and hyperglycaemia. This test is based on the specific glucose oxidase (GOD) – peroxidise (POD) reaction with a chromogen. Apart from glucose, no other compound in the urine is known to give a positive reaction. It is independent of pH and not affected by presence of ketone bodies. Test reactivity, however, decreases as the SG of the urine increases. Reactivity is inhibited by low temperature. Small amounts of glucose are filtered by healthy kidneys, therefore changes in the coloration of less than 50 mg/dL (2.8 mmol/L) are considered normal. The inhibitory effects of ascorbic acid has been largely eliminated for glucose readings higher than 150mg/dL. Other inhibitory substances include gentisic acid and pH values higher than 5. False positive results are usually caused by residues of peroxide, chlorine or tertiary ammonium compounds used as disinfectants, detergents or cleaning agents. The colour fields correspond to the following values: normal, 50, 150, 500 and ≥1000 mg/dL, or normal, 2.8, 8.4, 28 and ≥ 56 mmol/dL.
Interpretation: When a result falls between values, read to the nearest colour block. Repeat the test the following day when "trace values" are reported.
Detection range: 50 – 1000 mg/dL (2.8 – 56 mmol/L).

pH: Intended to estimate the pH of urine. Estimation of urinary pH is used to determine the alkalinity or acidity of urine and aids in the monitoring of patients on specific diets. Abnormal urinary pH values relate to many renal and metabolic disorders. Persistently high pH values may be indicative of urinary tract infections. The pH reaction is based on an indicator that changes colour from 5 to 9. The pH of healthy individuals varies between pH 5 and pH 6. Bacterial contamination may lead to false results. The colour fields correspond to the following values: pH 5, pH 6, pH 7, pH 8, and pH 9.
Interpretation: When a result falls between values, read to the nearest colour block.
Detection range: pH 5 – pH 9.

Reagent Composition
PRO: Tetrabromophenol blue 0.05%**;** Buffer 4.7%
GLU: GOD 2.1%; POD 1.0%**;** O-Tolidine 0.2%
pH: Methyl red 0.16%; BTB 0.18%

Storage and Stability
Urine reagent strips are packaged along with a drying agent contained in the cap of the plastic container. Containers must be kept tightly closed at all times. Keep product away from sunlight and humidity at all times. Store the containers in a cool dry place. Under proper conditions unopened test strips are stable up to the expiry date printed on the packaging. **Once opened, the product must be used within 6 months**.

Notes
- All results should be considered in conjunction with a proper clinical assessment. Positive results should preferably be confirmed by other laboratory methods. In the case of monitoring, results should always be discussed with a clinician before any action is taken.
- Do not interpret results after 60 seconds (120 seconds for leucocytes) as this may lead to false results.
- Do not allow urine or urine collection vessels to be contaminated by residues of cleaning agents or disinfectants, as these cause false-positive results.
- Measurements may not accurately reflect current conditions if the urine has been in the bladder for several hours.
- For single use only. Do not use more than once.
- The product is intended for professional use only, not for self-testing.
- Do not use with any fluids other than urine, including water.
- STORE IN A DRY PLACE AWAY FROM HEAT OR DIRECT SUNLIGHT. ALWAYS KEEP BETWEEN 2C and 30C
- Avoid contact with mucous membranes. Do not swallow.
- Please observe standard laboratory practice when handling urine reagent strips and urine. Always read results in good lighting conditions.
- It is recommended to use Negative and Positive Control Solutions in a quality control programme.
- Keep out of reach of children. Discard used strips in a medically and environmentally responsible manner.

Symbols and Abbreviations:

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Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

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