

URINE STRIPS

IVD

Cat. No.	Pack size
528 01 100	(100 test strip)
Uri-trak 1	For Glucose (100 test strip)
Uri-trak 2	For Glucose, ketones (100 test strip)
Uri-trak 3	For Glucose, protein, PH (100 test strip)

Intended Use

Uri-trak is a screening test strips for detection of glucose, ketones, protein and pH-value in urine. Certain configuration of strips may be read instrumentally, using the appropriate Urine Chemistry Analyzers.

Principle

Glucose: The detection is based on the glucoseoxidase-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 with sodium nitroprusside in alkaline medium a violet coloured complex.

Protein: The test is based on the „protein error“ principle of indicators. The test zone is buffered to a constant pH value and changes colour 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 9 (from orange to green to turquoise).

Reactive Ingredients

Glucose:
2% w/w glucose oxidase; 1% w/w peroxidase; 10% w/w TMB; 70% w/w Buffer; 17% w/w nonreactive ingredients.

Ketones:
5% w/w sodium nitroprusside; 95% w/w Buffer.

Protein:
0.2% w/w tetrabromophenol blue; 97.4% w/w Buffer; 2.4% w/w nonreactive ingredients.

pH:
0.2% w/w methyl red; 2.8% w/w bromothymol blue; 97% w/w nonreactive ingredients.

Specimen Collection

Use a fresh urine samples that is less than 2 hours old and place it in a clean, dry container. Do not centrifuge. The presence of usual urine preservatives will not affect the test results.

Instructions for use

Dip the test strip for approximately 1 second into the fresh urine. Draw it across the rim of the container to remove excess urine. After 30 to 60 seconds compare the test strip with the colour scale. The best time for comparison is after 30 seconds. Colour changes that take place after more than 2 minutes are of no significance. When tested the urine should not be older than 2 hours.

Evaluation - Sources of Error

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), neg. or normal (greenish), 50, 150, 500 and 1000 mg/dl or neg. (yellow), neg. or normal (greenish), 2.8, 8.3, 27.8 and 55.5 mmol/l

The influence of ascorbic acid (vitamin C) has been largely eliminated. An inhibitory effect is produced by gentisic acid. Falsely positive reactions can 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:
0 (negative), 25(+), 100(++) and 300(+++) mg/dl or
0 (negative), 2.5(+), 10(++) and 30(+++) 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.

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, 30, 100 and 500 mg/dl or negative, 0.3, 1.0 and 5.0 g/l
Falsely positive results are possible in alkaline urine samples (pH L 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 people varies between pH 5 and pH 6. The colour scale gives a clear distinction of pH value between pH 5 and pH 9.

Reagent Storage and Stability

Store at room temperature (15 to 30 °C) out of direct sunlight. Do not use after expiration date.

Precautions

The Kit contain a non-poisonous and harmless desiccant. In case this desiccant is swallowed accidentally, then drink plenty of water.

Disposal

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

Quality control

For Best results, performance of reagent strips should be confirmed by testing known negative and positive specimen or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. Each lab worker should ensure that it complies with government and local requirements.









Performance Characteristics

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of colour perception; the presence or absence of inhibitory and matrix factors typically found in urine; and the laboratory conditions in which the product is used (e.g., lighting, temperature, and humidity). Each colour block represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between normal levels may give results at either level. Results will usually be within one level of the true concentration. The following list shows the generally detectable levels of the analytes in contrived urines; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions.

Test pad and sensitivity (specificity)

Glucose: 50-100mg/dL (Glucose)
Ketone: 5-15mg/dL (Acetoacetic acid)
Protein: 15-30mg/dL (albumin)


SYMBOLS IN PRODUCT LABELLING

	For in-vitro diagnostic use
	Batch Code/Lot number
	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by

 Spectrum For Diagnostic Industries - Free Zone
Ismailia Free Zone, Block 5 .
Cairo- Port said Avenue.
Ismailia, Egypt
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com



IFUF528 Rev.(2), 4/2/2018

 MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany 