

# Medi-Test Keton

## Test strips for rapid detection of ketones in urine

### Instructions for Use

#### Application

Screening test for detection of metabolic anomalies.

The test is also suitable for use

- in preventive diagnosis (screening)
- for monitoring progress or relapse during therapy
- for self-monitoring by the patient.

Always discard damaged test strips or containers.

The stopper of the test strip container contains a non-toxic drying agent. If it is swallowed accidentally, drink plenty of water (if necessary contact a physician). Dispose used test strips with domestic waste (use test strips only once!).

See below for an explanation of the symbols on box and container label.

Store test strips out of reach of children!

These urine test strips serve exclusively for detecting morbid (pathological) changes in human urine.

#### Notes

Discuss **any positive** or **any unclear** results with your doctor. You must also do this if this test does not give a positive result, but the ailments persist.

If you suspect a false negative result, please repeat the test with a test strip from an unopened container or ask your physician. Your doctor will carry out further investigations with the usual methods in his laboratory. In principle, individual test strip results enable definitive diagnosis and targeted therapy only in combination with other medical findings.

Use only clean, well-rinsed containers to collect urine. Test urine preferably immediately after collection.

Always remove only the required number of test strips. Do not touch the test fields!

Tightly close container immediately after removal.

Do not remove the drying agent from the stopper, do not damage the stopper.

Protect test strips from sunlight and moisture. Store the container in a cool and dry place (do not refrigerate!) at a temperature between +4 and +30 °C (39 - 86 °F). The test strips can be used up to the imprinted expiry date if stored properly.

#### Explanation of symbols

Statement of Conformity (Product corresponds to the In-Vitro Diagnostic Medical Devices Directive 98/79/EC of the European Union)

Observe the instructions for use! (Read carefully before use!)

Storage temperature (4 to 30 °C / 39 to 86 °F) – storage at room temperature is recommended, direct exposure to sunlight must be avoided!

Can be used up to (do not use after the imprinted expiry date has elapsed!)

Batch marking

Catalogue number (for re-ordering)

#### Information and additional notes

##### Principle

The test is based on the principle of the Legal's test. Acetoacetic acid and acetone react with sodium nitroprusside in an alkaline medium to produce a violet colour complex.

##### Evaluation – Sources of error

The test is more sensitive to acetoacetic acid than to acetone. Values above 10 mg/dL acetoacetic acid or 50 mg/dL acetone are indicated. The colour fields are associated with acetoacetic acid concentrations as follows:

· 0 (negative), 25 (+), 100 (++) and 300 (+++) mg/dL or

· 0 (negative), 2.5 (+), 10 (++) and 30 (+++) mmol/L.

Phenyl ketones interfere in higher concentrations, but result in a different colour. β-hydroxybutyric acid is not detected.

Phthalein compounds produce reddish shades on the test field.

##### Reacting Substances

(Minimum quantity or activity/cm<sup>2</sup> when reaching the expiry date)

##### Ketones:

Sodium nitroprusside 116 µg

##### Notes

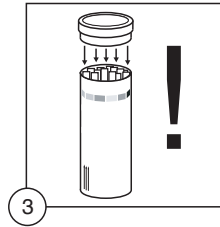
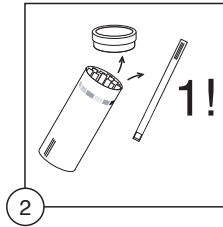
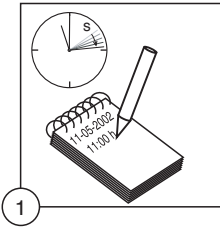
The effect of medications or their metabolites on the test is not known in all cases. In case of doubt it is therefore recommended to consult your physician.

Presentation: Packs of 50 and 100 test strips

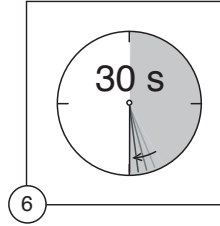
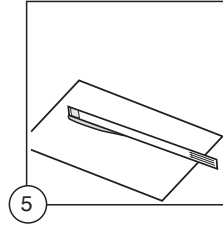
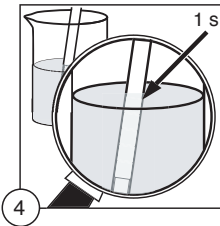
Date of revision: 11/2010

### Test procedure

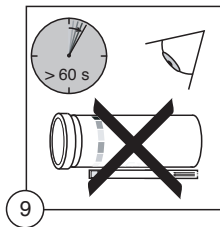
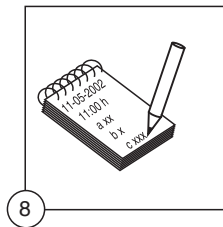
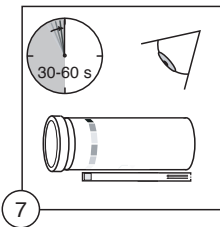
Follow this sequence exactly:



1. Provide clock with second hand. Note date and time.
2. Open container. Remove **one** test strip only. Do not touch reaction zone / test field!
3. Close container tightly immediately after removing test strip.



4. Immerse test strip in the urine for approximately 1 second. The test field must be submerged.
5. After removing the test strip from the urine sample, briefly dab the lateral edge on paper. Do not put the test strip down.
6. Wait for 30 seconds.



7. Start the evaluation:  
On the container label a colour sequence for the test field can be found. Arrows on the test strip and the container label show in which direction the test strip has to be aligned with the colour scale. Assign the test field to a colour value of the sequence. Find a match and select the colour value that comes as close as possible to the test field.
8. Note the results and submit them to your physician at your next visit.
9. Finish the evaluation within 60 seconds after immersion at the latest. Observe this time limit, since the test field still changes its colour intensity after this period.

**Discard test strip after evaluation.  
DO NOT use more than once!  
Never change the intake of prescribed medication as a result of this test.**