

Medi-Test Combi 2**Test strips for rapid detection of protein and glucose in urine****Instructions for Use****Application**

Screening test for early detection and monitoring of diabetes (diabetes mellitus) as well as infectious illnesses in the area of the kidneys and urinary tract. 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!)

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Information and additional notes**Principle**

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.

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.

Reacting Substances

(Minimum quantity or activity/cm² when reaching the expiry date)

Protein:
tetrabromophenol blue 7.5 µg

Glucose:
Glucoseoxidase 3.2 U
Peroxidase 0.2 U
o-Tolidine 65 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:12/2010

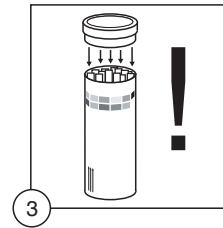
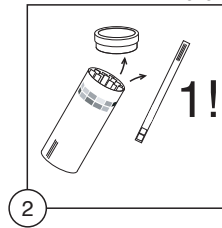
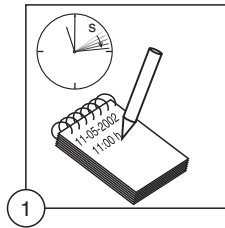
Evaluation – Sources of error

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 > 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.

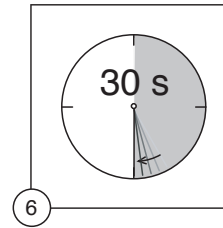
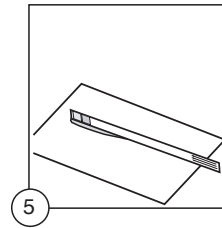
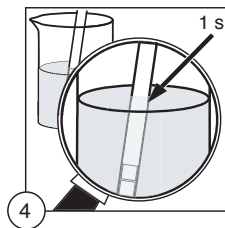
Glucose: Pathological glucose concentrations are indicated by a colour change from green to blue-green. Yellow to weakly green test fields are to be considered as negative (or normal). The colour fields correspond to the following glucose concentrations:
• 0 (negative), 20 (normal), 50, 150, 500 and ≥1000 mg/dL or
• 0 (negative), 1.1 (normal), 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.

Test procedure

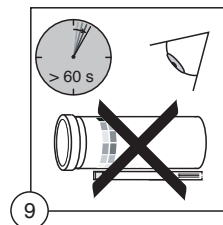
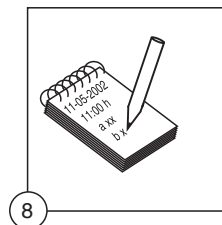
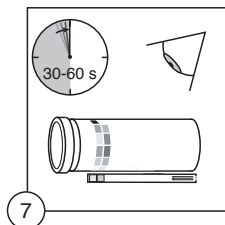
Follow this sequence exactly:



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



4. Immerse test strip in the urine for approximately 1 second. All test fields 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 each 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 each test field to a colour value of it's 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 some test fields still change their 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.