Medi-Test Combi 2

en

IVD in vitro-diagnostics, suitable for self-testing

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) and 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.

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 ... 30 °C (39 ... 86 °F). The test strips can be used up to the imprinted expiry date if stored properly. 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!

Explanation of symbols

- CE — Statement of Conformity (Product corresponds to the In-Vitro Diagnostic Medical Devices Directive 98/79/EC of the European Union)
- Please read instructions for use!
- Permitted storage temperature range
- Use by
- LOT — Batch identification
- REF — Item number
- Manufacturer
- Do not reuse

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 color 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.

Evaluation – Sources of error

Protein: Pathological protein concentrations are indicated by a color chane from light green to green (30, 100 and 500 mg/dL). The color 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 coloration may be masked by the presence of medical dyes (e.g. methylene blue) or beetroot pigments.

Glucose: Pathological glucose concentrations are indicated by a color change from green to blue-green (50, 150, 500 and ≥ 1000 mg/dL). Yellow to weakly green test fields are to be considered as negative (or normal). The color 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. False positive reactions can be caused by residues of peroxide -containing or other cleansing agents.

Quality Control in professional use

The performance of the test strips should be confirmed by use of positive and negative control solutions. Positive and negative controls should be analyzed once a day, whenever a new bottle of strips is opened, whenever a new lot of strips is started, and every 30 days to check storage conditions. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

Reacting Substances

(Quantity resp. activity/cm^2 at time of impregnation)

Protein:

tetrabromophenol blue	10 µg

Glucose:

glucose oxidase	7 U
peroxidase	1 U
tetramethylbenzidine	96 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

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Literature

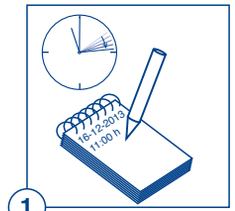
- Urinlabor, M. Zimmermann-Spinnler, Medical Laboratory Consulting, 1991.
- Labor und Diagnose, L. Thomas, TH-Books Verlagsgesellschaft, 2008.

MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6–8 · 52355 Düren · Germany
Tel.: +49 24 21 969-0 · Fax: +49 24 21 969-199 · info@mn-net.com · ***www.mn-net.com***

CE 0197

Durchführung des Harntests

Reihenfolge hierbei genau beachten:



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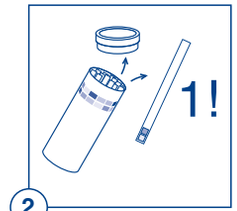

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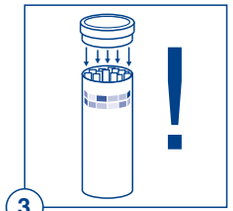

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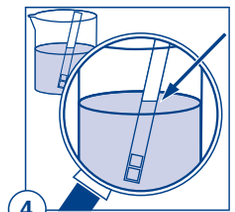
1. Uhr mit Sekundenanzeiger bereitlegen. Datum und Uhrzeit notieren.
2. Dose öffnen. Nur **einen** Teststreifen entnehmen. Reaktionszonen / Testfelder nicht berühren!
3. Dose nach der Entnahme sofort wieder fest verschließen.



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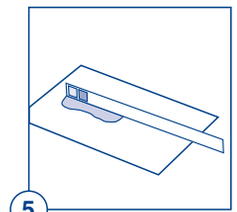

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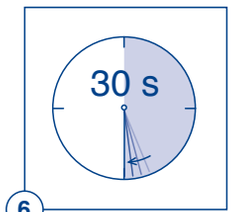

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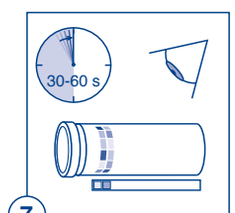
4. Teststreifen ca. 1 Sekunde in den Harn eintauchen. Die Testfelder müssen mit Harn benetzt werden.
5. Nach Herausziehen des Teststreifens aus der Harnprobe seitliche Kante auf Papier kurz abtupfen. Teststreifen nicht aus der Hand legen.
6. 30 Sekunden warten.



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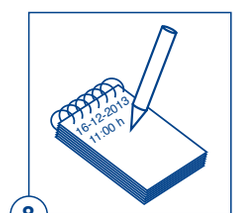

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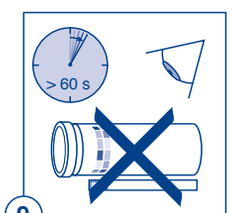

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7. Mit der Auswertung beginnen:
   Auf dem Dosenetikett befindet sich für jedes Testfeld eine Farbreihe. Jedem Testfeld ist ein Farbwert zuzuordnen. Wenn keine Übereinstimmung gefunden wird, ist der Farbwert zu wählen, der dem Testfeld am nächsten kommt.
8. Ergebnis notieren und Ihrem Arzt beim nächsten Besuch vorlegen.
9. Bewertung spätestens 60 Sekunden nach dem Eintauchen beenden. Diese zeitliche Begrenzung beachten, da das Testfeld seine Farbintensität auch danach weiter ändert.

Teststreifen nach der Auswertung wegwerfen.
NICHT mehrfach verwenden!
Ändern Sie **nie** die Einnahme der verordneten Medikamente aufgrund eines Resultats dieser Teststreifen.

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 / tests field!
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 color sequence for each test field can be found. Assign the test field to a color value of its sequence. Find a match or select the color value that comes as close as possible to the test field.
8. Note the result and submit it 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 color 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.