

Test strips for rapid detection of glucose in urine

Instructions for Use

Application

Screening test for early detection and monitoring of diabetes (diabetes mellitus).

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



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



Batch identification



Item number



Manufacturer



Do not reuse

Information and additional notes

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.

Evaluation – Sources of error

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.

Too low or false negative results are obtained as a result of increased quantities of ascorbic acid, which occur in the urine after a dose of vitamin C (e.g. vitamin pills, antibiotic preparations) as well as after consumption of fruit juice. Gentisic acid also exhibits an inhibiting effect. 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/cm² at time of impregnation)

Glucose:

Glucoseoxidase	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

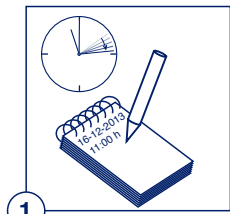
Date of revision: 10/2014

Ιελέργεια του τεστ ούρων

Παρακαλούμε να τηρείτε ακριβώς την ακολουθία:

Test procedure

Follow this sequence exactly:

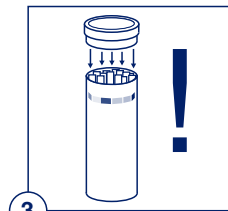


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1. Εφοδιαστείτε με ένα ρολόι με δευτερολεπτοδείκτης. Σημειώστε την ημερομηνία και την ώρα.
2. Ανοίξτε το κουτί. Πάρτε μόνο **μία** ταινία τεστ. Μην εγγίξετε τις ζώνες αντίδρασης / επιφάνειες τεστ!
3. Αμέσως μετά την λήψη κλείστε ξανά γερτά το κουτί.

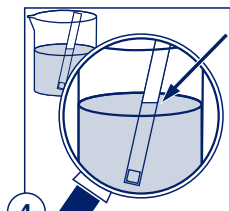


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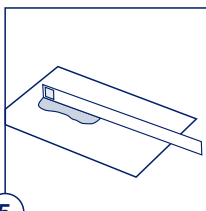
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1. Provide clock with second hand. Note date and time.
2. Open container. Remove **one** test strip only. Do not touch reaction zone / test field!
3. Close container tightly immediately after removing test strip.

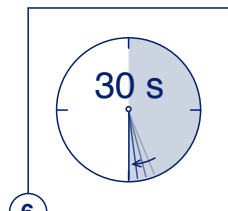


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4. Βυθίστε την ταινία τεστ περ. 1 δευτερόλεπτο στα ούρα. Όλες οι επιφάνειες του τεστ πρέπει να διαβραχούν με ούρα.
5. Μετά από το βγάλσιμο της ταινίας του τεστ από το δείγμα ούρων, σκουπίστε για λίγο την πλάγια πλευρά επάνω σε ένα χαρτί. Μην αφήσετε από το χέρι την ταινία του τεστ.
6. Αναμένετε 30 δευτερόλεπτα.

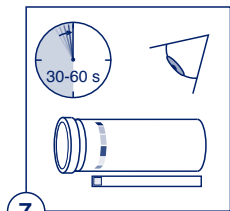


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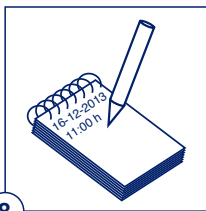
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4. Immerse test strip in the urine for approximately 1 s. The test field must be submerged.
5. After removing the test strip from the urine sample, briefly dab the lateral edge on paper. Do not put the test strip down.
6. Wait for 30 s.

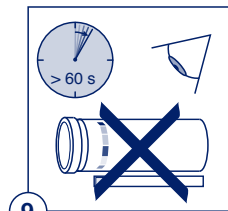


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7. Ξεκινήστε την μέτρηση: Στην ετικέτα του κουτιού βρίσκεται μία σειρά χρωμάτων για κάθε επιφάνεια του τεστ. Κάθε επιφάνεια του τεστ πρέπει να αντιστοιχεί σε μία χρωματική τιμή. Εάν δεν ευρεθεί ταύτιση, πρέπει να επιλέξετε την χρωματική τιμή, η οποία είναι πλησιέστερη της επιφάνειας του τεστ.
8. Σημειώστε το αποτέλεσμα και δείξτε το στον γιατρό σας στην επόμενη επίσκεψη.
9. Τερματίστε την μέτρηση το αργότερο 60 δευτερόλεπτα μετά την εμφύθιση. Προσέξτε αυτόν τον χρονικό περιορισμό, διότι διάφορες επιφάνειες του τεστ αλλάζουν και στην συνέχεια την ένταση του χρώματός τους.



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7. Start the evaluation: On the container label a color sequence for the 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 s after immersion at the latest. Observe this time limit, since the test field still changes its color intensity after this period.

Πετάξτε την ταινία του τεστ μετά την μέτρηση. Μην την χρησιμοποιείτε περισσότερο από μία φορά
Μην αλλάζετε ποτέ την λήψη των συνιστώμενων φαρμάκων λόγω ενός αποτελέσματος αυτών των ταινιών τεστ.

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