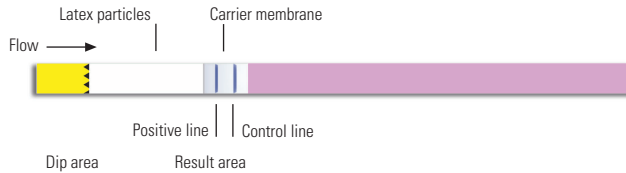


INSTRUCTIONS FOR USE

Structure of the dipstick



Intended use

The actim™ Pancreatitis test is a one-step dipstick test for use when acute pancreatitis is suspected. The test is based on detection of elevated levels of trypsinogen-2 in urine. The test is performed by immersing a dipstick in a urine sample.

Test components

The test package (32702ETAC) contains 20 dipsticks packed, together with desiccant, in an aluminum container. The dipsticks are ready for use.

Storage

Store the dipsticks refrigerated at +2 ...+8 °C. When the container is stored unopened, the dipsticks can be used until the expiry date marked on the label. The dipsticks can be used for 4 months after an aluminum container has been opened for the first time. However, the expiry date must not be exceeded.

Allow the aluminum container of dipsticks to reach room temperature before opening. Close the container immediately after removing the required number of dipsticks. Use the dipsticks shortly after their removal from the aluminum container, because moisture damages them.

Principle of method

Levels of trypsinogen-2 have been shown to increase in the urine of patients with acute pancreatitis.

The test is based on immunochromatography. It involves two monoclonal antibodies to human trypsinogen-2. One is bound to blue latex particles (the detecting label). The other is immobilized on a carrier membrane to catch labeled particles and indicate a positive result.

When the dip area of the dipstick is placed in a urine sample, the dipstick absorbs liquid, which starts to flow up the dipstick. If the sample contains trypsinogen-2 it binds to the antibody attached to the latex particles. The particles are carried by the liquid flow and, if trypsinogen-2 is bound to them, they bind to the catching antibody.

A blue line (positive line) will appear in the result area if the concentration of trypsinogen-2 in the sample exceeds the cut-off value for the test. A second blue line confirms correct performance of the test.

Performance of test

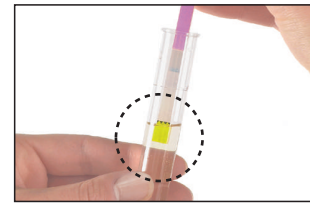
The cut-off value for the actim™ Pancreatitis test is such that the lowest detectable amount of trypsinogen-2 in the urine sample is 50 µg/l (Quantitative assay: Medix Biochemica Trypsinogen-2 IEMA TEST). This concentration gives a weak positive result.

Limitations of test

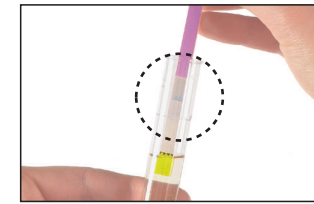
The test is intended for in vitro diagnostic use only.
The test is intended for professional use only.



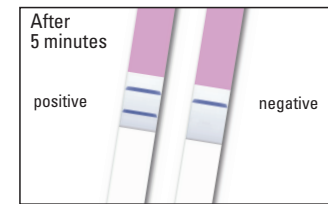
A. Dipping



B. Note upper limit of dip area



C. Note liquid front



D. Result

Brief instructions of use

Specimen

The specimen is urine. Urine samples should be tested as soon as possible after collection. Samples may be stored in a refrigerator at +2 ... +8 °C for one working day. If a sample needs to be stored for longer, it should be frozen. The sample should be brought to room temperature before testing.

Assay procedure and interpretation of results

1. Allow the aluminum container of dipsticks to reach room temperature before opening. Remove the required number of dipsticks from the container, and close it immediately. Do not touch the yellow dip area at the lower ends of the dipsticks. Identifying marks may be written on the upper pink parts of the dipsticks. Use the dipsticks soon after they have been removed from the aluminum container.
2. Allow the sample to reach room temperature before testing. Dip the yellow dip area (the lower end of the dipstick) into a sample and **hold it there until you see the liquid front enter the result area**. Do not dip beyond the line of black arrows that marks the upper limit of the dip area. Remove the dipstick from the solution and lay it horizontal.
3. The results are read **at 5 minutes**. However, a result can be interpreted as positive as soon as two blue lines become visible in the result area. If only one blue line appears within 5 minutes, the result is interpreted as negative.
Do not pay attention to any lines appearing later than 5 minutes.
4. If **two blue lines** appear, the test result is **positive**.
If **one blue line** appears, the test result is **negative**.
If **the control line does not** appear, the test is **invalid**.

Notes

- Do not use a dipstick that has become wet before use, because moisture damages the dipstick.
- Do not use a dipstick if you notice a blue coloring in the result area before testing.
- When dipping, be careful to hold the dipstick in position (with the dip area in the urine sample) until the sample liquid front reaches the result area. Do not leave the stick in the sample too long. The test will not work properly if the amount absorbed is too small or too large.
- Be careful not to dip beyond the dip area. The line of black arrows marks the end of the dip area.
- The positive line is in the lower half, the control line in the upper half of the result area of the dipstick. Appearance of a control line confirms correct performance of the test. If a control line does not appear, the test is invalid, and should be repeated using another dipstick.
- If the test result cannot be interpreted clearly (e.g. if the lines are blotched or uneven) it is recommended that the test be repeated with another dipstick.

- The result of a test should be interpreted as negative only after 5 minutes have elapsed. A faint blue line appearing after 5 to 10 minutes indicates a low trypsinogen-2 concentration, below the cut-off value for the test.
- As with all diagnostic tests, results must be interpreted in the light of other clinical findings.
- All biological specimens and materials must be treated as potentially hazardous, and disposed of in accordance with local authority guidelines.

Literature

Kylänpää-Bäck M-L, Kempainen E, Puolakkainen P, Hedström J, Haapiainen R, Perhoniemi V, Kivilaakso E, Korvuo A, Stenman U-H. Reliable screening for acute pancreatitis with rapid urine trypsinogen-2 test strip. *Br J Surg* (2000), 87:49-52.

Kempainen E, Hedström J, Puolakkainen P, Sainio V, Haapiainen R, Perhoniemi V, Osman S, Kivilaakso E, Stenman U-H. Rapid measurement of urinary trypsinogen-2 as a screening test for acute pancreatitis. *N Engl J Med* (1997) 336: 1788-1793.

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