



Microalbumin Urine Screening Test

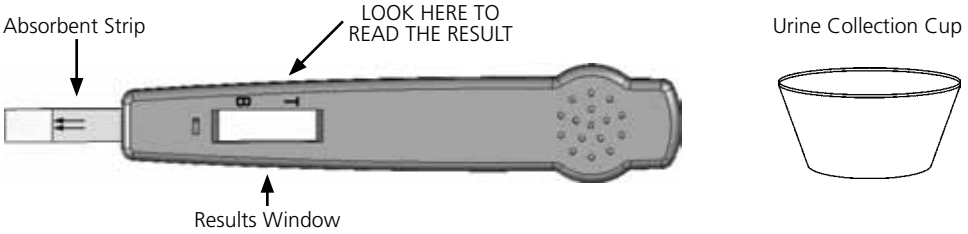
Contents of Package

- Foil Package (Contains: Test Device)
- Urine Collection Cup

Materials required but not provided:

- Clock with second hand or timer

Self Test Device
FOR *IN-VITRO* DIAGNOSTIC USE
NOT FOR INTERNAL USE



PLEASE READ CAREFULLY BEFORE BEGINNING TEST

Before You Begin the Test

Store the test at room temperature (15 - 30°C or 59 - 86°F).

Do not use the test after the expiration date printed on the package.

Do not open the foil pouch until ready to use. Once opened, use within 30 minutes.

If any part of the test device contents are broken or opened, do not use the kit.

Place the contents on a table or flat surface.

If you have any questions regarding the instructions or your results, please refer to the Question and Answer section on reverse side or call our Technical Service department at 800-854-3002.

Intended Use

The Fortel[®] Microalbumin Screening Test is for the detection of elevated levels of albumin in urine. Elevated urinary albumin is also known as microalbuminuria. Elevated albumin is an early sign of possible kidney damage. Detection of elevated urinary albumin can aid in the early detection and treatment of kidney disease in diabetics.

Instructions for Use

Collecting the Specimen

1. Collect urine sample in the cup provided.
2. Urine from any time of the day may be collected; however, optimal results will occur when testing first morning urine.
3. If test is not conducted immediately, urine may be stored in a refrigerator for up to 8 hours.

Running the Test

1. If the urine was refrigerated, bring to room temperature.
2. Tear open foil package by tearing along the slice on the package and remove the test device.
3. Dip the Fortel[®] Microalbumin Test into the urine.
IMPORTANT - Ensure that the urine covers up to the arrow line, but do not soak the plastic housing (figure 1).
4. Continue to dip the test device in the urine for 10 seconds (figure 2).
5. After 10 seconds, remove the test device and place on a flat surface.
6. Read the results after 10 minutes. **IMPORTANT** - Do not read the results before 10 minutes or after 15 minutes.

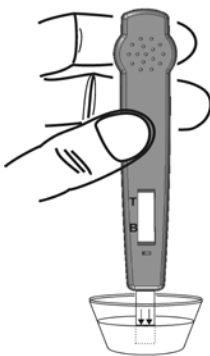


Figure 1

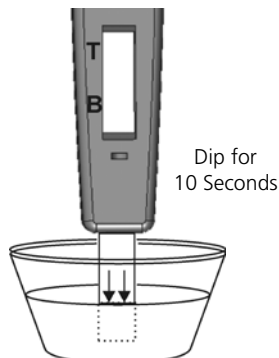


Figure 2

Continued on reverse side.

Reading the Test Results

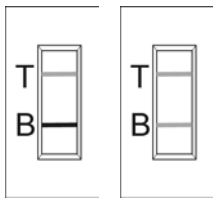
1. Look at the device - in the Results Window there is a Top Area marked with a "T" and a Bottom Area marked with a "B".
2. If two bands are present:

Strength of Bands	Result
Bottom band is darker than top band	NEGATIVE
Bands are equal	NEGATIVE
Top band is darker than bottom band	POSITIVE

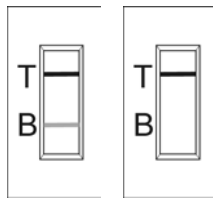
3. If less than two bands are present:

Strength of Bands	Result
Top band is present	POSITIVE
Bottom band is present	INVALID
No bands are present	INVALID

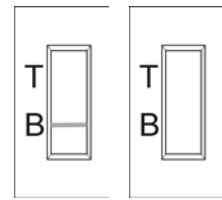
4. If lines are broken, result is invalid. If the test is invalid, a result cannot be obtained and the test must be repeated.
5. Contact your physician to discuss your test results.



Negative Result
Figure 7



Positive Result
Figure 8



Invalid Result
Figure 9

Limitations of the Test

- The Fortel® Microalbumin Urine Test is a screening test only. Additional testing will be needed for the final determination of microalbuminuria. **Note:** If the test result is positive, contact your doctor to discuss the results. Your doctor may decide to run additional tests.
- This test is intended for *in-vitro* (external) use only.
- Although the test is very accurate, no diagnostic test is 100% accurate. Always check with your physician if you get unexpected results.
- As with all self-testing devices, a definitive diagnosis should not be made on the basis of a single test. The diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated.
- This test device can only be used once. Discard it after use.
- Do not use after the expiration date on the package.
- The tests only works if the instructions are followed carefully.

Whether or not the test result is positive, if you have persistent symptoms of acute kidney failure, you should see your doctor. Symptoms of kidney failure include the following:

- Swelling of the legs and feet
- Little or no urine output
- Thirst and dry mouth
- Rapid heart rate
- Feeling dizzy when you stand up
- Loss of appetite, nausea, and vomiting
- Feeling confused, anxious and restless, or sleepy
- Pain on one side of the back, just below the rib cage and above the waist.

Questions and Answers

How does this test work (principle of method)?

The level of microalbumin present in urine is measured through the Fortel® Microalbumin Test. An elevated level of microalbumin may be an important signal of acute kidney failure. The test utilizes lateral flow technique in a single test device. This test is designed with a cut-off level of 18 mg/L.

What do I do if the test indicates a positive result?

This test is meant only as a screen. If you get a positive result, call your doctor and discuss the result. Your doctor may decide to run more tests.

What do I do if the test indicates a negative result?

This test is meant only as a screen. If you get a negative result, but do not feel well, call your doctor and discuss your symptoms. This test does not replace regular visits to your doctor.

How long do I have to wait to read the results?

The test results must be read after 10 minutes. The results are not valid if they are read after 15 minutes.

Why do I have to compare the intensity of the two lines?

The results of the Fortel® Microalbumin Test depend on the comparison of the intensity of the Top and Bottom lines.

What are the performance characteristics of the test?

The test showed a diagnostic accuracy of 95.7%, specificity of 97.8%, and sensitivity of 93.9% when compared to 94 confirmed samples.