

URINARY TRACT INFECTION (UTI) TEST

Instructions

EarlyDETECT™

The earlier, the better.

KIT CONTENTS

This **EarlyDETECT™** Screening Test includes:

- 3 sealed pouches containing 3 UTI nitrite reagent test strips and moisture absorbent packet for freshness
- Set of instructions
- Color Chart

Materials required but not provided:

- Clock or timer
- Collection cup

STORAGE & STABILITY

- Do not expose the **EarlyDETECT™** nitrite reagent test strips to direct light, moisture or liquid.
- Store the test pouch in a dry place between (15°–28°C, 39°–86°F)

BEFORE YOU BEGIN

This **EarlyDETECT™** test is intended for one use for each strip.

- Read product insert and directions carefully before each use.
- Do not open the pouch until you are ready to use the test.
- Do not touch the reactive nitrite reagent pad on the test strip.
- Do not let the test strip come into contact with any liquid prior to use.
- Discard test strips after use.

INTENDED USE

The **EarlyDETECT™** test detects nitrite in urine for the purpose of alerting the user to the possibility of a Urinary Tract Infection. The test by itself is not intended for use as the primary diagnostic method.

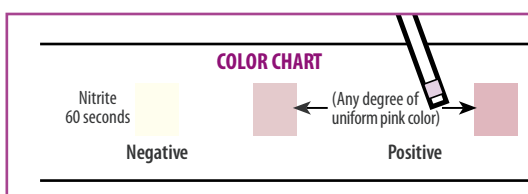
For *In Vitro Diagnostic Use Only*.

Nitrite is not a normal urine constituent. Nitrate and not nitrite is present in the urine primarily by dietary intake. The test depends upon the conversion of nitrate to nitrite by the action of gram-negative bacteria in the urine. The presence of nitrite in urine is abnormal and is an indication of urinary tract infection.

The **EarlyDETECT™** test provides a useful, convenient method of monitoring urinary tract infections. The test is recommended for use whenever a Urinary Tract Infection is suspected to provide preliminary results. Your physician may also recommend using the UTI test following treatment of Urinary Tract Infection to confirm the success of the treatment.

INSTRUCTIONS FOR USE

1. For most accurate results, use the test strip with your first morning urine.
2. Open one pouch and remove the UTI test strip.
3. Examine the test strip for any apparent damage. Check the color of the nitrite reagent pad; the color of the pad should be a buff, off-white/beige color. If the nitrite reagent pad is discolored (pink or any other dark color), do not use the test strips.
4. Turn the test strip so that the absorbent pad is facing up (towards you) and pointing down.
5. Hold the test strip and place the absorbent pad under your urine stream for 1 second, just enough to get the absorbent pad wet. It is important to avoid immersing the nitrite reagent pad in the urine stream for longer than 1 second.
5. Remove the excess urine from the nitrite reagent pad by gently shaking the test strip.
6. Compare the color of the test strip to the color chart provided and match carefully. Find the closest color match and read the test strip in one minute (60 seconds). Repeat the same procedure for the remaining test strips when ready to test again.



DO NOT READ TEST RESULTS AFTER 1 MINUTE.

INTERPRETING THE RESULTS

Expected Result: Normally, there is no detectable nitrite in the urine of a healthy individual and results with this test should be negative.

Negative (Normal): If there is no pink color on the test pad after 1 minute, this means that the test is negative. A negative result indicates that there is no detectable nitrite in the urine. If a negative result is obtained, but you are experiencing the symptoms of burning, painful urination, frequent urge to urinate, cloudy urine, unpleasant urine odor, abdominal discomfort, fever and/or lower back pain consult your physicians as soon as possible. False negative results may be obtained with the following conditions: Bacteria causing the Urinary Tract Infection does not produce nitrite. The urine collected may not have sufficient incubation time in the bladder for bacteria to convert nitrate to nitrite.

Positive (Abnormal): The appearance of any shade of pink color after 1 minute. A positive result means that nitrite is detected in the urine and indicates that there is a possibility of a Urinary Tract Infection. Consult your physician immediately if a positive result is obtained and you are experiencing the symptoms, such as burning, painful urination, frequent urge to urinate, cloudy urine, unpleasant urine odor, abdominal discomfort, fever and/or lower back pain. False positive results may be obtained with the following conditions:

- Contamination with compounds containing nitrite during handling and/or testing.
- Atypical color development (color not matching the color chart) may be obtained with dark (orange-reddish) urine.

LIMITATIONS OF THIS TEST

- The **EarlyDETECT™** test is not a conclusive test for Urinary Tract Infection, a physician must confirm positive results.
- The test provides a visual, qualitative test result only.
- Keep this product out of reach of children.
- Do not use after the expiration date printed on the pouch.
- Each test strip can only be used once. Discard after use.
- Although the **EarlyDETECT™** test has been demonstrated to detect nitrite in urine, there is the possibility for false positive and false negative results. Consult your doctor if you get unexpected or inconsistent test results.

PERFORMANCE CHARACTERISTICS

Studies have been conducted to confirm that the **EarlyDETECT™** Urinary Tract Infection (UTI) test for professional use and for home use are substantially equivalent.

70 samples (35 negative and 35 positive) were tested by laboratory technicians and selected consumers. The results are summarized below:

Consumer Accuracy: 96%

Laboratory Accuracy: 96%

Percent Agreement of Laboratory Results to Consumer Results: 100%

QUESTIONS & ANSWERS

Q: If I see a light pink color on the test pad, does this mean I have a UTI?

A: This means that the test is positive for nitrite and it is an indication that you probably have a UTI. You should consult your physician as soon as possible for a diagnosis and treatment plan.

Q: Can the test result change after standing for a certain length of time?

A: Yes, the test will change if left standing for more than 3 minutes. Read the test result within 1 minute and discard. Do not read the test after 1 minute.

Q: If the test is positive, what do I do?

A: If the test is positive, you should see your physician as soon as possible.

Q: If the test is negative, what do I do?

A: If the test is negative, this means that nitrite was not detected in the urine. However, if you are experiencing symptoms of Urinary Tract Infection (burning, painful urination, frequent urge to urinate, cloudy urine, unpleasant urine odor, abdominal discomfort, fever and/or lower back pain) you should consult your physician as soon as possible.

Q: Can I get a false or misleading result?

A: This should not happen if you follow the instructions correctly. However, if you get the absorbent pad wet before using the test, then you may not get a reliable result. Certain rare medical conditions can also cause a false result. If you repeatedly get unexpected results, you should consult your doctor.