ABOUT THE TEST

The URI-TEST Nitrite in Urine detects nitrite in urine. Nitrite indicates the presence of certain bacteria that are commonly associated with Bladder/Urinary Tract Infection. Normally, urine is sterile (no bacteria) and therefore no nitrite is present. The test depends upon the conversion of nitrate (derived from the diet and usually present in urine) to nitrite by the action of bacteria in urine. By performing the test yourself at home, you may detect a possible urinary tract infection sometimes before symptoms are noticed.

Any pink color that develops on the sensor pad indicates a positive reaction and means that you have nitrite in your urine. You should immediately consult your physician. Your physician will make a diagnosis and can prescribe an appropriate course of treatment. The clinical symptoms of Bladder/Urinary Tract Infection may include burning, frequent or cloudy urination, unpleasant urine odor, abdominal discomfort, fever and lower back pain. If you have any of these symptoms and your Test Strip is NEGATIVE - immediately consult your physician.

PRECAUTION: THIS PRODUCT DETECTS NITRITE IN THE URINE FOR THE PURPOSE OF ALERTING YOU AND YOUR PHYSICIAN TO THE NEED FOR FURTHER EVALUATION. NITRITE MAY APPEAR IN URINE WHEN BACTERIA IS PRESENT IN THE URINE. ADDITIONAL TESTING IS NECESSARY TO CONFIRM POSSIBLE INFECTION AND DETERMINE PROPER MEDICAL ACTION. THIS TEST CANNOT BE USED BY ITSELF TO DIAGNOSE URINARY TRACT INFECTION OR DETERMINE TREATMENT.

Under certain conditions and when used properly this test can tell you if you have bacteria in your urine. Bacteria is an indication of Urinary Tract Infection. A normal or abnormal result with this test means very little by itself. It is only one piece of information your doctor needs in order to treat you. You should talk to your doctor any time that you have symptoms, even if your test result is normal.

CONTENTS OF THE KIT

Nitrite Reagent Test Strips
Plastic Collection Cups
Color Chart
Product Instructions

Test Strips are ready to use from the package and are completely disposable. The Sensor Pad located on the Test Strip is impregnated with 25% w/w Arsanilic Acid, 10% w/w N-1 Naphthylethylendiamine Dihydrochloride and 65% w/w Tartaric Acid. The Test Strips are stable when stored at room temperature until the expiration date as stated on the package.

PROPER USE AND STORAGE

DO NOT OPEN THE PACKAGE IN A STEAMY BATHROOM.
Open the foil package and remove the Nitrite Test Strip. Do not open until ready to use.
Do not touch the Sensor Pad.
Do not let the Test Strip come in contact with any liquid prior to use.
Store kit in a dry place below 86°F (30°C). Do not store in the refrigerator.
Do not re-use Test Strip.
Discard Test Strip after use.

DIRECTIONS FOR USE

For most accurate results, use your first morning urine or a urine sample at least four hours after last urinating.

1. Collect fresh urine in a clean plastic cup (included). Collected urine should be tested as soon as possible. If sample is not tested immediately, urine can be stored in the refrigerator (2-8°C) for up to 8 hours. If you store your urine, before testing, let the urine stand at room temperature or 15-20 minutes.
2. DO NOT OPEN IN A STEAMY BATHROOM. Remove the Nitrite Test Strip from the individual foil package.
3. Examine the Test Strip prior to use. The sensor pad should be a buff (white/beige) color. Discard if sensor is damaged or discolored.
4. Completely immerse the test area of the Test Strip in fresh urine.
5. After wetting the Test Strip with urine, tap the Test Strip against the side of the container.
6. Wait 60 seconds. Compare the color of the Test Sensor Pad to the Color Chart provided.

WHEN READING, HOLD THE TEST STRIP CLOSE TO THE COLOR BLOCKS AND MATCH COLOR CAREFULLY.

IMPORTANT NOTE: IGNORE COLOR CHANGES THAT OCCUR AFTER THREE MINUTES

READING THE RESULT

NORMAL/NEGATIVE: After 60 SECONDS, compare the Sensor Pad to the Color Chart provided. If no pink color appears, the TEST RESULT IS NEGATIVE. No pink color indicates that there is no detectable nitrite in your urine and that the test is negative. A negative result does not always mean that you have no bacteria present in your urine. There are several possible causes of false negative results including:

* Bacteria causing the infection does not produce Nitrite.
* When urine has not been retained in the bladder long enough (an estimated four hours) the bacteria may not have sufficient time to reduce nitrate to nitrite.
* Use of antibiotics or Vitamin C.
* When dietary nitrite is absent, even if the organisms containing reductase are present and incubation in the bladder is ample, the absence of nitrates in urine may be due to unusual dietary conditions, i.e. a diet free of vegetables.

IMPORTANT: WHEN READING, MATCH THE SENSOR PAD TO THE COLOR CHART PROVIDED. IF THE TEST IS NEGATIVE AND YOU CONTINUE TO EXPERIENCE ANY ABNORMAL SYMPTOMS, YOU SHOULD SEE YOUR PHYSICIAN.
**EXPECTED VALUES**

Normally, there is no detectable nitrite in urine. If no pink color is observed on the sensor pad, as compared to the Color Chart provided, the test is negative. A positive result is indicated by a color change, from white to any shade of pink (i.e. the sensor pad is a darker pink than the negative block on the Color Chart). A positive result indicates you have nitrite in your urine. Nitrite is produced by bacteria that commonly cause urinary tract infection.

- **Negative:** No pink color observed
- **Positive:** Any shade of pink

After testing, write down your test results so that you can discuss them with your physician. If you have a negative test result and you continue to have symptoms of a Bladder/Urinary Tract Infection, contact your physician immediately. The clinical symptoms of Bladder/Urinary Tract infection may include burning, frequent urgency to urinate, cloudy urine, unpleasant urine odor, abdominal discomfort, fever and/or lower back pain. If you have any questions concerning your test result call 1-800-482-2907.

**STUDIES HAVE BEEN DONE TO CONFIRM THE PERFORMANCE OF THE URI-TEST NITRITE TO ANOTHER COMPARABLE PRODUCT. THE FOLLOWING IS A SUMMARY OF THE TEST RESULTS AND PERFORMANCE DATA:**

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<thead>
<tr>
<th></th>
<th>BAYER +</th>
<th>BAYER -</th>
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</thead>
<tbody>
<tr>
<td>TCPI +</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>TCPI -</td>
<td>0</td>
<td>76</td>
</tr>
</tbody>
</table>

- **Sensitivity:** >99%
- **Specificity:** 89.41%
- **Accuracy:** 91.09%

It is important to note the accuracy of Nitrite as an indicator of Urinary Tract Infection has been well documented in the literature. Accuracy of Urine Nitrite determination has been reported in the literature to be 50-60%. See Bibliography for references.

**GUIDELINES FOR USE**

- **ABNORMAL/POSITIVE:** Wait 60 SECONDS and compare the SENSOR PAD to the Color Chart provided. If any shade of pink color appears on the sensor pad the test is **POSITIVE**. The appearance of colors other than pink may be related to the presence of certain dietary, or therapeutic dyes or blood in your urine. If you have any questions about the result please call 1-800-482-2907.

**LIMITATIONS**

1. URI-TEST Nitrite in Urine is not a conclusive test for infection. Positive results MUST be confirmed by your physician.
2. Large amounts of Vitamin C or fruit juices (Ascorbic Acid) and/or antibiotic therapy can lead to false positive results.
3. False negative or false positive results or the occurrence of a color other than a pink color may be the presence of certain dietary or therapeutic dyes or blood in the urine.
4. False negative results could be related to infection by a bacteria that does not reduce nitrate.
5. False negative results could be related to frequent urination (urine not held in the bladder for at least four hours) and the bacteria is unable to reduce nitrates to nitrites.

**PRODUCT PERFORMANCE**

**EXPECTED VALUES**

- **Normal Values:** Negative
- **Positive:** Any shade of pink
- **Negative:** No pink color observed

It is important to note the accuracy of Nitrite as an indicator of Urinary Tract Infection has been well documented in the literature. Accuracy of Urine Nitrite determination has been reported in the literature to be 50-60%. See Bibliography for references.

**BIBLIOGRAPHY**