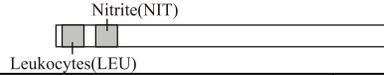


Urinary Tract Infection Test Strips Package Insert For Self-Testing

PRINCIPLE

The UTI Urinary Tract Infection Test Strips are for the detection of Leukocytes and Nitrite in urine. It is used as an aid in the screening of urinary tract infection (UTI). The test is a firm plastic strip onto which Leukocyte and Nitrite test pads are attached. If the test is positive, the Leukocyte test pad should be beige to dark purple, and the Nitrite test pad should be uniform pink to red.

REAGENT COMPOSITION



| Reagent | Read Time | Composition | Description |
|-------------------------|-----------|--|---|
| Leukocytes (LEU) | 2 minutes | derivatized pyrrole amino acid ester; diazonium salt; buffer; non-reactive ingredients | Detects leukocytes as low as 9-15 white blood cells $Leu/\mu L$ in clinical urine |
| Nitrite (NIT) | 1 minute | p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients | Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid |

WARNING AND PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For urine testing only. Do not use for blood testing.
- Do not use after the expiration date.
- Keep out of the reach of children.
- For *in vitro* diagnostic use. Not to be taken internally.
- The used strip should be discarded according to local regulations after testing.

STORAGE AND HANDLING

- Store in a dry place at 2-30°C (36-86°F). Do not freeze. Keep out of direct sunlight.
- The strip should remain in the closed bottle or the sealed pouch until use.
- Do not transfer the strips to another bottle. Do not remove the desiccant from the bottle.
- Record the date on the bottle label when the bottle was first opened. Discard the bottle 3 months after first opening it. Constant exposure to air may cause inaccurate readings.
- Do not use if pouch is torn or damaged.
- Do not touch the test pad(s) of the strip. Discard any discolored strips that may have deteriorated.

MATERIALS PROVIDED

- Strips
- Package insert
- Color chart

MATERIALS REQUIRED BUT NOT PROVIDED

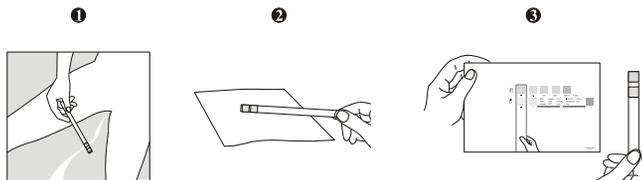
Timer or watch with second hand Absorbent material (e.g. paper towel) Specimen collection container (optional)

INSTRUCTIONS

Allow the strip and urine specimen to reach room temperature (15-30°C or 59-86°F) prior to testing. Gently wash the genital area thoroughly with soap and water then rinse well prior to testing.

1. Remove the strip from the closed bottle or the sealed pouch, and use it as soon as possible. Close the bottle tightly after removing the required number of strip(s).
2. Hold the end of the strip farthest away from the test pad(s) and begin urinating. After 1 or 2 seconds of passing urine, hold the strip downward with the test pads pointing into the urine stream for 1-2 seconds. Make sure the test pads are completely wet. See illustration 1.
Note: If you prefer, you can urinate into a clean and dry container. Dip the test pad(s) of the strip completely into the urine for 1-2 seconds and remove immediately. Run the edge of the strip against the rim of the urine container to remove excess urine.
3. After removing the strip from your urine, immediately bring the edge of the strip into contact with an absorbent material (e.g. paper towel) to remove excess urine. Lay the strip with the test pad(s) facing upwards and begin timing. See illustration 2.
4. **Read result at 1 minute for Nitrite and at 2 minutes for Leukocytes.** Compare the test pad(s) to the color blocks on the color chart. Hold the strip close to the color blocks, and carefully match each pad to the color chart for that test. See illustration 3.

Note: Do not read results after 3 minutes.



READING THE RESULTS

Read the results by comparing the test pad(s) to the color blocks on the color chart. Match the color of the test pad to the closest color block on the color chart.

| Color Chart Reading | Reagent | Results | | | |
|------------------------|------------|--|--|--|---|
| | LEU NIT | - or ± | - or ± | +, ++, or +++ | +, ++, or +++ |
| | | - | + | + | - |
| Recommendations | | Results suggest no sign of UTI. When trace (±) LEU occurs or if you have symptoms, test again the following day with your first morning urine using a new strip. If you get another trace (±) LEU or if you still have symptoms, consult your physician. | Results suggest a sign of UTI. Consult your physician immediately. | Results suggest a sign of UTI. Consult your physician immediately. | Results suggest a sign of UTI. Repeat the test next time you urinate using a new strip. Make sure to wash the genital area first. If LEU is still positive, consult your physician. |

LIMITATIONS

There is the possibility that this test may produce false results. Consult your physician before making any medical decisions. Note: The test may be affected by substances that cause abnormal urine color such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin. The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.

1. **Leukocytes:** The drug tetracycline may cause a false negative result. High protein or elevated glucose in urine may cause test results to be low.
2. **Nitrite:** Any degree of uniform pink to red color should be read as a positive result. Pink spots or pink edges should not be read as a positive result. High ascorbic acid may cause test results to be low.
Note: You may get a negative result if you have a UTI caused by bacteria that does not change nitrate to nitrite, when urine has not been held in the bladder for more than 4 hours, when taking antibiotics, or when your diet does not include nitrates.

QUESTIONS AND ANSWERS

1. **Q: What are the common symptoms of UTI?**
A: The common symptoms of UTI include burning or pain during urination, frequent urination, fever, and back or groin pain.
2. **Q: Can I have UTI without symptoms?**
A: Yes. UTI can occur without symptoms in young children, pregnant women and the elderly.
3. **Q: Do I have to test with first morning urine?**
A: Although you can test at any time of the day, your first morning urine would have the most bacteria in it if UTI is present. Avoid testing during your menstrual period.
4. **Q: How accurate is the test?**
A: The results of the UTI Urinary Tract Infection Test Strips were compared to another commercial test. The study showed 94.4% accuracy for the Leukocyte test and 98.4% for the Nitrite test.
5. **Q: Do certain foods, alcohol or common medications affect the test?**
A: In general, most substances will not interfere with the test. Consult your physician if you are taking antibiotics. Some medications (e.g. Vitamin B2) can affect the color of your urine and may cause false results. Large quantities of Vitamin C may cause false negative results.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the strips are based on both laboratory and clinical tests. The sensitivity of the test depends upon several factors: the variability of color perception; the presence or absence of inhibitory factors; and the lighting conditions under which the strip is read.

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