

Atlas Home Urinary Tract Infection Test (UTI)

For In-Vitro Diagnostic and self testing Use
Store At room temperature (15-30°C)



INTRODUCTION:

Urinary tract infection is a serious health problem affecting millions of people each year. The urinary system consists of the kidneys, ureters, bladder and urethra. The kidneys remove excess liquid and wastes from the blood on the form of urine, keeping a stable balance of salts and other substances in the blood. Narrow tubes called ureters carry urine from the kidneys to the bladder, which is a triangle-shaped chamber, in the lower abdomen. Urine is stored in the bladder and emptied through the urethra.

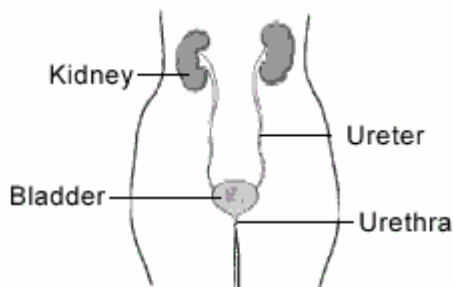


Figure 1: Urinary Tract Anatomy

The average adult passes between 0.8 and 2.6 L per day. The amount of urine varies, depending on the fluids a person consumes. The volume formed at night is about half that formed in the daytime.

Normal urine is sterile; it contains fluids, salts and waste products, but it is free of bacteria, viruses and fungi. An infection occurs when microorganisms, usually bacteria from the digestive tract, cling to the opening of the urethra and begin to multiply.

In most cases, bacteria first begin growing in the urethra. An infection limited to the urethra is called urethritis. From there, bacteria often move on to the bladder, causing a bladder infection called cystitis. If the infection is not treated promptly, bacteria may then go up the ureters to infect the kidneys. This infection is called pyelonephritis.

The urinary system is structured in a way that helps ward off infection. The ureters and bladder normally prevent urine from backing up toward the kidneys, and the flow of urine from the bladder helps wash bacteria out of the body. In men, the prostate gland produces secretions that slow bacterial growth. In both sexes, immune defenses also prevent infection. But despite these safeguards, infections still occur.

Escherichia coli (E.coli), a type of bacteria that is normally present in the colon, causes about 80% of urinary tract infections (UTI) in adults. These bacteria may enter the urethral opening from the surrounding skin. Other bacteria that cause urinary tract infections include Staphylococcus, Chlamydia and Mycoplasma.

Urinary tract infections are more common in women than in men. One reason for this is related to the fact that their urethral opening is nearer to the source of bacteria (e.g. anus and vagina) and their urethra is shorter, providing bacteria easier access to the bladder. Other factor is due to the fact that prostate gland in men produces secretions that decrease bacterial growth as mentioned earlier.

Certain conditions may increase the risk of developing a urinary tract infection. The most important ones are:

1. Bladder outlet obstruction, such as kidney stones or prostate gland enlargement in men.
2. Urinary catheterization (i.e. insertion of a small tube into the bladder through the urethra to drain urine).
3. Abnormalities of the urinary tract that is present at birth.
4. Suppressed immune system.
5. Conditions that cause incomplete bladder emptying such as spinal cord injury.
6. In infants, bacteria from soiled diapers can enter the urethra and cause UTI by introducing bacteria in the urinary tract.

Pregnant women seem to be no more prone to UTIs than other women. However, when a UTI does occur, it is more likely to travel to the kidneys. Scientists think that hormonal changes and shifts in the position of the urinary tract during pregnancy make it easier for bacteria to travel up the ureters to the kidneys. For this reason, many doctors recommend periodic testing of the urine during pregnancy.

Symptoms of urinary tract infection can be divided into two groups; symptoms of lower UTI (Cystitis and Urethritis) and symptoms of upper UTI (pyelonephritis).

Symptoms that indicates lower UTI in adults include the following:

1. Back pain
2. Blood in the urine
3. Cloudy urine
4. Inability to urinate despite the urge
5. Fever
6. Frequent need to urinate
7. General discomfort
8. Painful urination

Symptoms that indicate upper UTI in adults include the following:

1. Chills
2. High fever
3. Nausea (A feeling of sickness in the stomach characterized by an urge to vomit)
4. Pain below the ribs
5. Vomiting

INTENDED USE:

In the urine analysis test, the urine is examined for white blood cells (Leukocytes), red blood cells (RBCs) and bacteria. This is usually done using a microscope. White blood cells are a type of blood cells that are responsible for defending the body against any invader, so it is considered as a first sign for any infection in the body. Its presence in the urine indicates that the infection is taking place some where in the urinary tract. When the infection occurs, white blood cells move from the capillaries around the urinary tract and enter the lumen of it to kill the bacteria present there. This movement may be some times associated with the movement of red blood cells due to the increased permeability of the capillaries. This increased permeability is important to facilitate the movement of white blood cells. Certain types of Bacteria (among them the E.coli) have the ability to generate Nitrite; this fact is used to test for bacteria in urine by testing the presence of Nitrite. Atlas Urinary Tract Infection Check test provides a dip-and-read test strips that are intended for use to check for Leukocytes, RBCs and nitrite in urine specimens as an aid in the diagnosis of UTI. The test provides results by the visual comparison with color chart printed on the pack. An interesting point that is considered as an advantage of Atlas

UTI check test over using the microscope to detect White blood cells is the ability of Atlas UTI check test to detect either intact or lysed white blood cells. This is because the strip can detect an enzyme that is secreted from the leukocyte, so even if they are lysed, the enzyme will still be available.

KIT COMPONENTS:

1. Test strips individually pouched.
2. Package Insert.

STORAGE:

Store at room temperature between 15°-30° (59°F-86°F). Do not store the strips in the refrigerator or freezer.

Since the test strips are sensitive to specific environmental factors, such as moisture, heat and light, do not expose strips to these factors.

Use the strip immediately after removing it from the pouch.

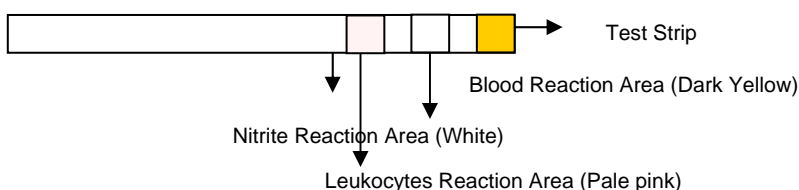
SPECIMEN COLLECTION AND PREPARATION:

Collect a clean catch urine sample by washing the genital area and collect a midstream sample of urine in a clean and dry disposable container. The container has to be devoid of any detergent traces. This method of collecting urine helps prevent bacteria around the genital area from getting into the sample and confusing the test results. Test the urine as soon as possible after collection. A first morning urine specimen is recommended for nitrite test.

PROCEDURE:

This procedure **MUST BE FOLLOWED EXACTLY** to achieve reliable test results.

1. Check that the product is within the expiration date shown on the kit pack.
2. Prepare the urine specimen.
3. Remove the strip from the pouch. Familiarize yourself with the position of the reaction area of Leukocytes, RBCs and Nitrite. Pale pink reaction area is for Leukocytes, white is for nitrite and dark yellow area is for blood. Also, familiarize yourself with the color chart on the pack



4. Dip the test strip in the urine until the reaction areas are completely immersed for no more than 1 second.
5. Remove the dipstick from the urine and tap the strip on the rim of the cup to remove excess urine and place it horizontally with the reaction areas facing up.
6. Leave the strip for 30-60 seconds for the reaction to take place.
7. Read the results by comparing the colors of the reaction on the strip with those of the chart. While comparing, keep the strip in a horizontal position to avoid possible mix of colors between the reaction areas on the strip.
8. Identify the best match color on the color chart and the correspondent concentration range. A change in color that appears only along the edges of the reaction areas indicates that the reaction did not take place properly so we recommend redoing the test with another strip. Results read after 60 seconds are not valid.

RESULTS:

The results are obtained by direct comparison of test strip with the color chart printed on the pack. See the table below for test interpretation and recommendations.

LIMITATIONS OF THE TEST:

Substances that cause abnormal urine color, such as some drugs may affect the color development on the strip. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted visually as a false positive. It is therefore recommended that in case of doubt, the test should be repeated after stopping the medication.

Leukocytes: The test result may not always be consistent with the leukocyte cell number by the microscopic examination. Positive results may be found with high humidity and high temperature condition, and failure of the bottle security. Positive results may occasionally be found in random specimens from females due to contamination of the specimens by the vaginal discharge.

Nitrite: Any degree of uniform pink color development should be considered positive, however, pink spots or pink edges should not be interpreted as a positive result. Color development is not proportional to the number of bacteria present. The urine test detects only nitrite-producing bacteria. Occasionally bacteria will be present that do not produce nitrite. Therefore, a negative result cannot rule out the presence of urinary tract infection.

Blood: A false positive can sometimes occur when bacteria are present in the urine. Ascorbic acid or protein may reduce the reactivity of the blood test. Strong oxidizing substances, such as hypochlorites, may produce a false positive result. Urine from menstruating females often, but not always, yields positive results.

HOW TO DETERMINE POSITIVE OR NAGTIVE VALUES:

Any color other than the color indicating negative result is considered positive. Refer to the results chart.

PRECAUTIONS & WARNINGS

1. Please read all the information in this leaflet before performing the test.
2. Do not use the test after the expiration date.
3. If the package is not completely sealed do not use the test.
4. Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
5. The test should be performed in a well-lit area.
6. Use the test device immediately after opening it.
7. Do not touch the test area. This could affect results and may also impose personal hazards.
8. Use a disposable sample container to be discarded after performing the test.
9. The pouch contains a Silica Gel pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
10. Do not freeze.
11. At the end of the test, wrap every thing you have used in a plastic bag and throw away in the pin. Do not forget to wash your hands properly.
12. The remaining sample should be discarded and flushed in the toilet.
13. Keep out of the reach of children.
14. For *in vitro* diagnostic and self-testing use. Not to be taken internally.

QUESTIONS AND ANSWERS:

Q: Is there any changes on the appearance or color of urine that may indicate UTI?

A: In case of severe infection, the urine is cloudy due to the presence of large numbers of bacteria and leukocytes. As for the color, it will be more to a reddish color in the presence of blood. However, small amounts of blood will not affect the color. An important point in this regard is that this appearance may be associated with other conditions such as kidney stones. So, performing a more specific test is advised.

Q: How kidney stones and prostate gland enlargement increase the risk of UTI?

A: These two conditions will result in slowing the urine flow out of the body, which will give bacteria better chance to get inside the urinary tract and cause infection.

Q: How is UTI treated?

A: UTIs are treated with antibacterial drugs. The choice of drug and length of treatment should be determined by a physician and depends on the patient history and the urine tests that identify the offending bacteria. The sensitivity test is especially useful in helping doctors to select the most effective drug.

Q: How long it takes to treat a UTI?

A: Often, UTI can be cured within 1 or 2 days of treatment. Still, many doctors ask their patients to take antibiotics for a week or two to ensure that the infection has been completely cured. Patients also need longer treatment with infections caused by Mycoplasma or Chlamydia. In men, doctors usually recommend longer therapy than in women. This is done to prevent infections of the prostate gland since prostate infections are harder to cure because antibiotics are unable to penetrate infected prostate tissue effectively.

Q: How can I monitor UTI therapy?

A: Using Atlas UTI Check Test, you can redo the test after treatment and monitor the result using the chart above.

Q: Will UTIs come back?

A: Most healthy women do not have repeat infections. However, about one out of every five women who get a UTI will get another one. Some women get three or more UTIs a year. Men get repeat infection more frequently. Anyone who has diabetes or a problem that makes it difficult to urinate may get repeat infections.

Q: How can I keep from getting more UTIs?

A: Changing some of your daily habits may help you avoid UTIs.

1. Drink lots of fluids to flush the bacteria from your system. Water is best. Have 6-8 glasses of water per day.
2. Drink cranberry juice or take vitamin C. Both increase the acid in your urine so bacteria cannot grow easily. Cranberry juice also makes your bladder wall slippery, so bacteria cannot stick to it.
3. Urinate frequently and go when you first feel the urge. Bacteria can grow when urine stays in the bladder too long.
4. Wear cotton underwear and loose-fitting cloths so that air can keep the area dry. Avoid tight-fitting jeans and nylon underwear, which trap moisture and help bacteria grow.
5. Take showers instead of tub baths.

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Urinary Tract Infection (UTI) Result Chart

