Actorfemme™ Home Urinary Tract Infection Test (UTI)
For *in vitro* diagnostic and self testing use
Store at room temperature (15-30 ºC)

INTENDED USE

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 waste from the blood in 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.

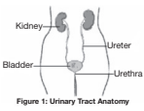


Figure 1: Urinary Tract Anatomy

The average adult passes between 0,8 and 2,6 liters of urine 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 returning 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 (UTIs) 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 because the female urethral opening is nearer to the source of bacteria (i.e. anus and vagina) and the urethra is shorter, providing bacteria easier access to the bladder. Another factor is that the 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 significant are:

1. Bladder outlet obstruction, such as kidney stones or prostate gland enlargement in men.
2. Urinary catheterisation (i.e. insertion of a small tube into the bladder through the urethra to drain urine).
3. Abnormalities of the urinary tract 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 nappies can enter the urethra and cause UTIs by introducing bacteria in the urinary tract.

Pregnant women do not seem to be more prone to UTIs that other women. However, when a UTI does occur in pregnant women, 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 indicate lower UTI in adults include the following:

- Back pain
- Blood in the urine
- Cloudy urine
- Inability to urinate despite the urge
- Fever
- Frequent need to urinate
- General discomfort
- Painful urination

Symptoms that indicate upper UTI in adults include the following:

- Chills
- High fever
- Nausea
- Pain below the ribs
- Vomiting

COMPONENTS

- Test strips in individual pouches
- Desiccant
- Patient Information Leaflet

PRECAUTIONS & WARNINGS

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

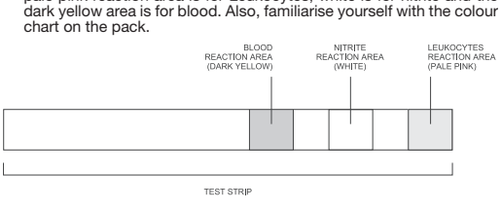
SPECIMEN COLLECTION AND PREPARATION

Collect a clean catch urine sample by washing the genital area. 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 a 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 test pack.
2. Prepare the urine specimen.
3. Remove the strip from the pouch. Familiarise yourself with the position of the reaction area for Leukocytes, RBCs and Nitrite. The pale pink reaction area is for Leukocytes, white is for nitrite and the dark yellow area is for blood. Also, familiarise yourself with the colour chart on the pack.



4. Dip the test strip into 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.

RESULTS

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

Leukocytes	Nitrite	RBCs	Result
Positive	Positive	Positive	You have a urinary tract infection. There is presence of bacteria. The presence of blood is associated with severe infections. Seek medical assistance immediately.
		Negative	You have a urinary tract infection. There is presence of bacteria. Seek medical assistance immediately.
	Negative	Positive	You have a urinary tract infection. You might have bacteria that cannot produce nitrite. Presence of blood is associated with severe infections. Seek medical assistance immediately.
		Negative	You have a urinary tract infection. You might have bacteria that cannot produce nitrite. Seek medical assistance immediately.
Negative	Positive	Positive	This result is highly unlikely to occur and we recommend redoing the test. If you have the same result again, this means that you most probably have a urinary tract infection since there is presence of bacteria. Presence of blood is associated with severe infections. Seek medical assistance immediately.
		Negative	This result is highly unlikely to occur and we recommend redoing the test. If you have the same result, this means that you have a urinary tract infection as there is presence of bacteria. Seek medical assistance immediately.
	Negative	Positive	No urinary tract infection. The presence of blood may be associated with other conditions such as kidney stones, excessive exercise, prostate diseases (in males) and some kidney or blood diseases. Seek medical assistance.
		Negative	No urinary tract infection.

LIMITATIONS OF THE TEST

Substances that cause abnormal urine colour, such as some drugs, may affect the colour development on the strip. The colour development on the reagent pad may be masked, or a colour 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, that the test be repeated after stopping the medication.
Leukocytes: The test result may not always be consistent with the leukocyte cell number by microscopic examination. Positive results may be found with high humidity and high temperature conditions, in cases where the pouches may not have been adequately sealed. Positive results may occasionally be found in random specimens from females due to contamination of the specimens by vaginal discharge.
Nitrite: Any degree of uniform pink colour development should be considered positive; however, pink spots or pink edges should not be interpreted as a positive result. Colour 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 a 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 NEGATIVE VALUES

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

QUESTIONS AND ANSWERS

Q: Are there any changes in the appearance or colour of urine that may indicate UTI?
A: In case of severe infection, the urine may be cloudy due to the presence of large numbers of bacteria and leukocytes. As for the colour, it will take on a reddish colour in the presence of blood. However, small amounts of blood will not affect the colour. 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 do 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 a 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 does it take to treat a UTI?
A: Often, symptom relief can be experienced 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 eradicated. 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 treat because antibiotics are unable to penetrate infected prostate tissue effectively.

Q: Can UTIs recur (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 infections more frequently. Anyone who has diabetes or a condition 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.

- Drink lots of fluids to flush the bacteria from your system. Water is best. Have 6-8 glasses of water per day.
- 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.
- Urinate frequently and go when you first feel the urge. Bacteria can grow when urine stays in the bladder for too long.
- Wear cotton underwear and loose-fitting clothing so that air can keep the area dry. Avoid tight-fitting jeans and nylon underwear, which trap moisture and help bacteria grow.
- Take showers instead of tub baths.

STORAGE

Store in the original packaging, at room temperature below 25 ºC.
Do not use after the expiry date on the packaging.
KEEP OUT OF REACH OF CHILDREN.
Use the strip immediately after removing it from the pouch.

PRESENTATION

Each carton contains 2 individually packaged UTI test strips.

NAME AND ADDRESS OF DISTRIBUTOR:

Actor Pharma (Pty) Ltd