ASTAM DIAGNOSTICS

PRODUCT INSERT

REF UTIS

PRATHAM®

URINARY TRACT INFECTION (UTI) TEST STRIPS

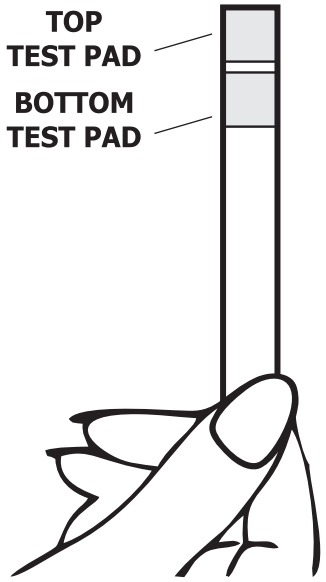
INTENDED USE

PRATHAM® Urinary Tract Infection (UTI) 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.

INTRODUCTION

PRATHAM® Urinary Tract Infection (UTI) Test Strips can help detect if you have a urinary tract infection (UTI). This information will allow you to take an active role with your physician in the management of your health. The urinalysis test strips test for Leukocytes (White blood cells) and Nitrite for greater reliability.

REAGENT COMPOSITION



REAGENT	READ TIME
Nitrite (NIT)	1 minute
Leukocytes (LEU)	2 minutes

COMPOSITION

- **NITRITE (mg/dL) :** This test is based on diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt with an aromatic compound on the reaction pad.
- **LEUCOCYTES (WBC/µL) :** Granulocytic leucocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydrozy-5-phenyl pyrrole.

KIT COMPONENTS

1. Pouch contents:
   Test Strip, Desiccant
2. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer and Urine collection container (optional) etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

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.

TEST PROCEDURE

Allow the strip and urine specimen to reach room temperature (15-30ºC or 59-86ºF) prior to testing.

1. Remove the strip from the sealed pouch, and use it as soon as possible.
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 fo 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.

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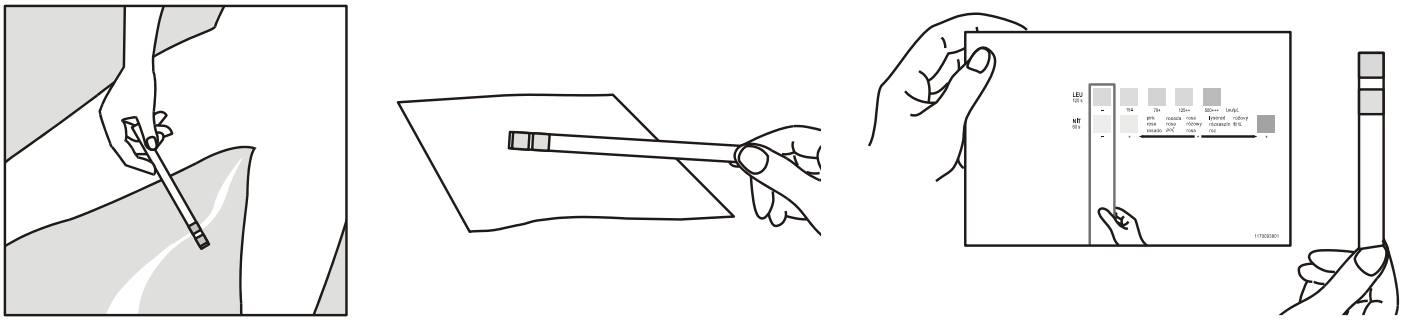

INTERPRETATION OF RESULTS

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 closet color block on the color chart.

LIMITATIONS

There is the possibility that this test may procedure 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 Gantonol®), 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 be bacteria that does not change nitrate to nitrite, when urine has not been held in the bladder for more than 4 hours, when taking antibodies, or when your diet does not include nitrates.

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 of absence of inhibitory factor; and the lighting conditions under which the strip is read.

DISPOSAL

Consider all test strips run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

QUALITY CONTROL

- For best results, performance of reagent strips should be confirmed be testing known positive and negative specimens / controls.
- Test QC as per your laboratory policies and follow local, state and federal regulations.
- Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips. Please not: Water is NOT an appropriate negative control.
- Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; when clinical conditions or symptoms do not match the results obtained on the test strips.

REFERENCES

1. A.H. Free and H.M. Free "Urinalysis critical discipline of clinical science "CRC Critical Reviews in Clinical Laboratory Sciences, 481-531,1972.
2. H. Free et. Al., "A comparative study of qualitative tests for ketones in urine and serum" Clin. Chem., 4,323,1958.
3. J.M. Wilson and G.Hunger "Principles and practice of screening for disease "Public Health Papers Bo. 34, World Health Organization, Geneva, 1986.

SYMBOLS USED ON LABELS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:

ASTAM DIAGNOSTICS PVT. LTD.

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