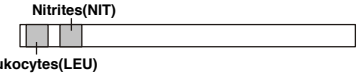
Urinary Tract Infection Test

Self-test • strips • urine • leukocytes & nitrites rapid test

ENGLISH

[PRINCIPLE]
The Urinary Tract Infection Test is used for the detection of leukocytes (LEU) and nitrites (NIT) in urine. It is used as an aid in the screening of a Urinary Tract Infection (UTI). The test is a firm plastic strip onto which leukocyte and nitrites test pads are attached. If the test is positive, the leukocyte test pad should present beige to dark purple, and the nitrites test pad should present uniform pink to red.

[REAGENTS COMPOSITION



Positive samples of each analyte were confirmed by the reference method and then diluted to the lowest "**positive**" concentrations indicated on the colour chart. For each analyte, aliquots of the lowest positive samples were further diluted to 80%, 60%, 50% and 25% of the originals with negative urine.

Urine samples including negative and all spiked and diluted samples were tested with three lots of the Urinary Tract Infection Test strips. Each sample was tested with each lot in 21 replicates by 3 operators each day for 3 consecutive days.
Read results by comparing colour reaction to the colour blocks according to the instructions on the package insert. The percentages of positive results were calculated.
The minimum sensitivity level for each analyte of the Urinary Tract Infection Test is defined as the lowest level at which over 67% (2/3) of the test results are positive when the diluted positive samples for an analyte of known concentrations were tested.

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/uL in clinical urine.
Nitrite (NIT)	1 minute	p-arsanilic acid; N-1(1-naphthyl)-ethylendiamine; 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 only. 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 or 36-86°F. Do not freeze. Keep out of direct sunlight.
• The strip should remain in the sealed pouch until use.
• Do not transfer the strips to another pouch. Do not remove the desiccant from the pouch.
• Constant exposure to air may destroy reagents on the strip causing inaccurate readings.
• Do not use if pouch is torn or damaged.
• Do not touch the test pad(s) of the strip. Discard any discoloured strips that may have deteriorated.

[MATERIALS PROVIDED]

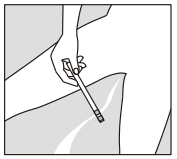
[INSTRUCTIONS]
Allow the strip and urine specimen to reach room temperature (15-30oC) prior to testing. Gently wash the genital area thoroughly with soap and water then rinse well prior to testing.

1.Remove the strip from the sealed pouch and hold absorbent tip facing downwards in urine stream or in a collected urine sample for 1-2 seconds. Make sure the test pads are completely wet. See illustration 1.

2. Remove the tip from the urine and place the test stick on 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.

3. **Read result at 1 minute for Nitrites and at 2 minutes for Leukocytes.**

4. Match the colour of the test strip pads to the colour blocks on the colour chart to carefully match each pad to the colour chart for that test.
See illustration 3.

1.


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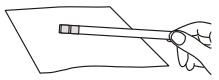

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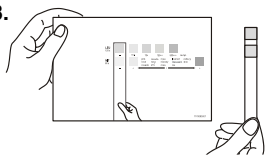

Colour Chart Reading	Reagent	Leukocytes (LEU)			
	Leukocytes (LEU)	– or ±	– or ±	+, ++, or +++	+, ++, or +++
	Nitrites (NIT)	–	+	+	–
Summary of Results		Leukocytes: Negative Nitrites: Negative	Leukocytes: Negative Nitrites: Negative	Leukocytes: Negative Nitrites: Negative	Leukocytes: Negative Nitrites: Negative
Leukocytes (LEU)		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 o fUTI. 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 colour such as drugs containing azo dyes (e.g. Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.[1] The colour development on the test pad may be masked or a colour 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. Nitrites
• Any degree of uniform pink to red colour 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.
• Negative results may occur if the urinary tract infection is caused by a bacteria that does not change nitrate to nitrites; when urine has not been held in the bladder long enough (at least 4 hours); when taking antibiotics; or when your diet does not include nitrates.

[EXTRA INFORMATION]
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 period.
4. Q: How accurate is the test?
A: The results of the UTI Urinary Tract Infection test strips were compared to another commercial UTI test. The study showed a 94.4% accuracy for the Leukocyte test and 98.4% for the Nitrites test.
5. Q: Do certain foods, alcohol or common medications affect the test?
A: In general, most substances will not interfere with the test. You should consult your physician if you are taking antibiotics. Some medications (e.g. Vitamin B2) can affect the colour of your urine and may cause false results. Large quantities of Vitamin C may cause false negative results. We suggest that you limit your Vitamin C intake for at least 24 hours before you perform the test.

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

Accuracy
Urine samples from 125 subjects (66 Female, 59 Male) were tested using the Urinary Tract Infection tests. The same samples were tested on another commercially marketed UTI strip and the results were compared.

Urinary Tract Infection Test Strips Visual read method vs. Predicates device reading		
Analyte	Visual % Agreement ±1 Colour Block	95% Confidence Interval
Leukocytes	94.4% (118/125)	89% - 98%
Nitrites	98.4% (123/125)	94% - 99%

Consumer Study
A consumer study was performed to test the accuracy of layperson result when compared to those of a trained professional.

Urinary Tract Infection Test Strips Visual Read Lay Persons vs. Professionals		
Analyte	Visual % Agreement ±1 Colour Block	95% Confidence Interval
Leukocytes	99.2% (124/125)	96% - 99%
Nitrites	>99% (125/125)	97% -100%

[BIBLIOGRAPHY]
1. Henry JB, et al. *Clinical Diagnosis and Management by Labouratory Methods, 20th Ed. Philadelphia.* Saunders. 371-372, 375, 379, 382, 385, 2001.

Index of symbols

	Consult instructions for use	Σ	Contains sufficient for <n> tests		Manufacturer
IVD	In vitro diagnostic medical device		Use by		Do not reuse
2°C 30°C	Temperature limit	LOT	Lot Number	REF	Catalogue number
EC REP	Authorized representative in the European Community				

CE 0123

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