

REAGENT PAD TEST STRIPS FOR URINE SELF-TESTING

This is a package insert to be used for Urinalysis products.

The reagent pads test qualitatively and semi-quantitatively for the presence of leucocyte and nitrite in urine.

Self-testing in vitro diagnostic use. Single use only, do not reuse. Dispose of respectfully.

IF YOU HAVE SYMPTOMS, TALK TO YOUR HEALTH PROFESSIONAL.

SUMMARY

Urinalysis test strips are a firm plastic with two affixed reagent pads, one testing for nitrite and the other for leucocytes in urine. Please refer to colour chart to indicate positive and negative appearance. Nitrite test pad can detect the presence of bacteria in urine. Bacteria should not normally be present in urine, the presence of bacteria is indicative of a urinary tract infection. Leucocyte reagent will detect if there are white blood cells (leucocytes) present in the urine. Leucocytes become apparent to fight infections, therefore when leucocytes are detected in urine indicate an infection is likely present. A positive result for both nitrite and leucocyte indicates a urinary tract infection is imminent.

Urinalysis test strips are individually contained in an aluminium pouch. A dehydration desiccant packet is also contained within each pouch to keep the strip dry to eliminate risk of damage from humidity. Each strip is ready for use as soon as it is removed from its pouch. The reagent strip is for single use only. Results are obtained from visual interpretation by comparing the colour of the reagent pads on the test strip to the colour chart located on the aluminium pouch the strip came in. No calculations or laboratory instruments are required.

TEST PRINCIPLE

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to form a diazonium compound in an acid medium. The diazonium compound couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink colour.

Leucocytes: This test is based on the action of esterase present in leucocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple colour.

REAGENTS

Nitrite: 1.4% w/w *p*-arsanilic acid, balanced with buffer and nonreactive ingredients.

Leucocytes: 0.4% w/w indoxyl ester derivative; 0.2%w/w diazonium salt; 99.4% w/w buffer and nonreactive ingredients.

WARNINGS AND PRECAUTIONS

Urinalysis reagents are for in vitro diagnostic use meaning they are for external use only. Do not touch the reagent pads. Touching pads will cause contamination and results may not be accurate. Package contents may be disposed of in normal waste disposal after use.

All package contents are non-toxic and safe when used as advised.

Do not use if package punctured.

As with all diagnostic tests, a definitive diagnosis should not be based on the result of a single test, your health professional will require pathological evaluation before administering treatment.

STORAGE

Store at room temperature between 2°-30°C and out of direct sunlight. Do not use after expiration date printed on the foil pouch. The recommended shelf life is 12 months.

SPECIMEN COLLECTION AND PREPARATION

Urine directly onto reagent pads on test strip. Alternatively urine can be collected in a sterile container then immerse the reagent pad end of the test strip into collected urine sample immediately. If testing cannot be performed within one hour after urinating, protect from contaminants and refrigerate the specimen immediately. Allow refrigerated specimen to return to room temperature before testing. Using urine preservatives is not recommended.

MATERIALS

Each test strip is individually sealed in a foil pouch.

Each box contains

1. 2x one individually packaged urine test strip (inside pouch)
2. Desiccant (inside pouch)
3. Colour chart (outside pouch)
4. Information package insert
5. Outer paper box

HOW TO USE

1. Remove strip from the pouch for immediate use.
2. Completely immerse reagent areas of the strip in fresh urine for only a few seconds until test pads are wet with urine.
3. Wait for times given for results to occur. Nitrite results will appear 1 minute after urine sample provided. Leucocyte results will appear 2 minutes after urine sample provided.
4. Compare both reagent squares to their corresponding colour blocks on the colour chart (located on foil pouch which contained strip).
5. Obtain results by direct colour chart comparison.

Note: Please read the results in these time frames. Proper read time is critical for optimal results. If the result is read after the times mentioned, the strips may no longer be accurate.

RESULTS

Results are obtained by direct comparison the colour blocks with colour chart. The colour blocks represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURE

As with all tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

Nitrite: The pink colour is not quantitative in relation to the number of bacteria present. Any degree of pink colouration should be interpreted as a positive nitrite test suggestive of 10^5 or more organisms/ml. Urinary tract infections from other pathogens can occur, this will not be indicated by nitrite. Absence of dietary nitrite can also cause false negative results.

Negative nitrite results can appear yet a urinary tract infection can still be present. If nitrite results appear at all positive please consult your doctor.

Leucocytes: False positive results can occur if the when taking antibiotics; cephalexin, tetracycline and gentamicin. High urinary protein and or glucose can decrease the reactivity of results causing a false negative reaction. False positive results can occur due to contamination from vaginal fluid. Pregnancy may also skew results. If leucocyte results appear at all positive please consult your doctor.

If one of the parameters, nitrite or leucocyte are positive still seek health practitioner consultation.

EXPECTED VALUES

Nitrite: Normally no detectable amount of nitrite is present in urine. The longer the urine is in your bladder, the longer the bacteria have to grow and results will become more accurate. It is highly recommended to wait a minimum of 4 hours from when you last urinated to when taking the test. It is also recommended to perform test on first urine in the morning if possible, as the urine has been retained in the bladder over night.

Leucocytes: Normal urine specimens generally yield negative results with this test. A positive result small or great is a indicator of infection. Trace results are more clinically significant with repeated positive results.

EXPECTED CONCENTRATION RANGE

Test items	Test Unit	Expected Test Concentration					
		–	±	1+	2+	3+	4+
Leucocytes	cells. µL-1	0	15	70	125	500	
Nitrite		–	+				

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance characteristics of Urinalysis test strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity and accuracy. Generally, reagent strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. (See LIMITATIONS OF PROCEDURE)








For visually read strips, accuracy is subjective to the person reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye.

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SYMBOLS EXPLAINED

-  For in vitro diagnostic use
-  Use By
-  Consult instruction for use
-  Lot number
-  Store at 2°C~30°C
-  Do not reuse
-  Manufacturer

Urinalysis Pty Ltd
1/62 Woodlands Road Katoomba 2780
NSW, Australia
Urinalysisaustralia.com.au
admin@urinalysisaustralia.com.au

 Yercon Diagnostic Co.,Ltd
3248 The Century Avenue 130033 Changchun,China
yerconlab@yerconlab.com Tel: +86 431 84698368