

One Step THC Test Strip For Urine

INTENDED USE

The one step THC (Tetrahydrocannabinol) test is a simple one step immunochromatographic assay for the rapid, qualitative detection of THC and its metabolites 11-nor-9-tetrahydrocannabinol-9-carboxylic acid in urine. The cutoff of the test is 50 ng/ml of THC (11-nor-9-tetrahydrocannabinol-9-carboxylic acid). It is the same as the SAMHSA recommended assay cutoff.

The THC test provides only a preliminary analytical result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography, mass spectrometry (GC/MS) is the preferred method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

EXPLANATION OF THE TEST

THC (9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When ingested or smoked, it produces euphoric effects. Users have impairment of short-term memory and THC use slows learning. Also, it may cause transient episodes of confusion, anxiety, or even toxic delirium. Long term, relatively heavy use may be associated with behavioral disorders. The peak effect of smoking THC occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-9-tetrahydrocannabinol-9-carboxylic acid.

The THC test is based on the principle of the highly specific immunochemical reactions between antigens and antibodies, which are used for the analysis of specific substances in biological fluids. The sensitivity is 50 ng/ml of THC.

MATERIALS PROVIDED

The THC test kit contains the following items to perform the assay:

1. THC test cassette.
2. Instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Clock or timer.

PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Avoid cross contamination of urine samples by using a new urine specimen container and for each urine sample.
3. Urine specimens are potentially infectious. Proper handling and disposal methods should be established according to good laboratory practices.
4. Do not eat or smoke while handling specimen in the laboratory.
5. The THC device should remain in its original sealed pouch until ready for use.
6. Do not use the test if the pouch is damaged or the seal is broken.
7. Do not use the test kit after the expiration date.

STORAGE AND STABILITY

The THC test kit should be stored at 4-30 °C in the original sealed pouch. The expiration date given was determined under normal laboratory conditions.

SPECIMEN COLLECTION AND PREPARATION

1. Fresh urine specimens do not require any special handling or pretreatment.
2. Specimens should be collected in a clean glass or plastic container.
3. If testing will not be performed immediately, specimens should be refrigerated.
4. Specimens should be brought to room temperature before testing.
5. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

PROCEDURE OF THE TEST

1. Remove the test strip from its foil pouch.
2. Holding the strip vertically, carefully dip it into the specimen. Do not immerse the strip past the maximum line (Figure 1).
3. Interpret test results at 3 to 5 minutes.

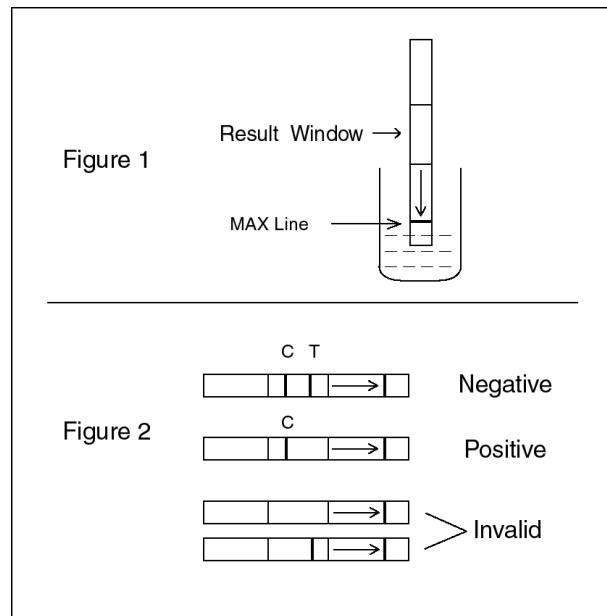
INTERPRETATION OF THE TEST

1. As the test kit begins to work, a color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band. **Note: Due to the chemical nature of the THC, the color of the Test band is much fainter comparing to the color of the Test band of other drugs of abuse tests. Therefore, it is best to read a test under sufficient amount of lighting.**

2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

NEGATIVE: TWO COLOR BANDS

The appearance of two color bands within the result window indicates a negative test result. No THC above the cut-off level has been detected. **The color of the Test band may be lighter or darker than that of the Control Band.**



POSITIVE: ONE COLOR BAND

The appearance of only one color band within the result window indicates the result is positive, i.e. the specimen contains THC at a concentration above the cut-off level.

INVALID:

A distinct color band should always appear in the left section of the result window. The test is invalid if no color band forms in the left section of the result window.

Note: Due to the chemical nature of the THC, the color of the Test band is much fainter comparing to the color of the Test band of other drugs of abuse tests. Therefore, it is best to read a test under sufficient amount of lighting.

USER QUALITY CONTROL

Control standards are not supplied with this kit; however, it is recommended that a control be tested as good laboratory testing practice. For information on how to obtain controls, contact Technical Service. Before using a new kit with patient specimens, positive (cutoff and 25% more than cutoff level) and negative (25% below cutoff level) controls should be tested to confirm the test procedure, and to verify the tests produce the expected Q.C. results.

LIMITATIONS

1. The test is designed for use with unadulterated human urine only.
2. There is a possibility that factors such as technical or procedural errors, as well as other substances in the urine samples may interfere with the test and cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the method of analysis. If adulteration is suspected, the test should be repeated with a new sample.
4. A positive test result does not provide any indication of the level of intoxication or urinary concentration.
5. The test results read after 5 minutes may not be consistent with the original reading obtained within the 5 minutes reading period. The test must be read within 5 minutes of sample application.
6. Prolonged passive smoking of THC may also produce a positive result.

EXPECTED VALUES

The THC test is a qualitative assay. The amount of drugs and metabolites present in the urine cannot be estimated by the assay. The assay results distinguish positive from negative samples. A positive result indicates the sample contains THC above the cutoff concentration.

PERFORMANCE CHARACTERISTICS AND COMPARISON STUDIES

The THC test has been shown to detect an average of 50 ng/ml or more of THC metabolites in urine. The accuracy of the THC was evaluated in comparison to a commercially available immunoassay. A total of 50 negative real patient urine samples (THC concentration range of 0-34 ng/ml) and 50 positive real patient urine samples (THC concentration range of 50-730 ng/ml) were tested by both procedures. Complete agreement was observed in 100% of the samples. All positive and part of the negative samples were confirmed by GC/MS.

PRECISION AND REPRODUCIBILITY STUDIES

The precision of the THC assay was determined by carrying out the test with serially spiked THC urine samples. The four concentrations, of 0 ng/ml, -25% from the cutoff (37.5 ng/ml), cutoff (50 ng/ml) and +25 % from the cutoff (62.5 ng/ml) were tested to challenge the precision of the test device. A total of 50 tests were run at 0 concentration, 50 at 37.5 ng/ml, 200 at 50 ng/ml and 50 at 62.5 ng/ml. In all 350 tests were tested. About 99% of the samples containing drug concentrations at or more than 25% over the cut-off level consistently showed positive results.

The reproducibility studies were carried out at three different sites. The urine samples containing 0, 50 ng/ml and 150 ng/ml of THC were tested with a total of 360 THC test kits. The samples were tested two times in the same day, and with two different assays, each day for 20 days. This permits separate comparisons of between-day, between-assay and within-day results, which show good consistency.

CUTOFF STUDIES

There are a total of 200 urine samples including 50 samples containing zero, 50 samples -25% below the cutoff (37.5 ng/ml), 50 samples at the cutoff (50 ng/ml) and 50 samples at 25% above the cutoff (62.5 ng/ml). Both the commercially available immunoassay test kit tested all 200 urine samples. Complete agreement was observed at 99.5% and the test cutoff established at 50 ng/ml of THC.

SPECIFICITY AND INTERERENCE STUDIES

The following table lists compounds that are detected by the THC test. The results are expressed in terms of the concentration required to produce a positive result.

Compound	Conc. (ng/ml)
Cannabinol	150,000
11-nor-8-THC-9-COOH	50
11-nor-9-THC-9-COOH	50
8-Tetrahydrocannabinol	25,000
9-Tetrahydrocannabinol	10,000

Potentially interfering chemicals such as pain medication (Acetaminophen, 20 mg/dl), protein (2000 mg/dl), glucose (2000 mg/dl), hemoglobin (500 mg/dl) and pH of 6.0, 7.0 and 8.0 were supplemented to normal urine specimens devoid of THC. The test gave consistently negative results. The base line urine with 50 ng/ml THC scored consistently positive.

REFERENCES

1. R.C. Baselt, Disposition of Toxic Drugs and Chemicals in Man, 2 and ED, Biomedical Publ, Davis, CA., p. 488, 1982.
2. Urine Testing for Drugs of Abuse, National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.