

One Step THC Cassette Test Kit
For Urine
(Revised May 28th, 2002)

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 urine. Major antibodies and buffers used in the THC Test Kit listed as following: Goat anti-rabbit IgG (Control Line), mouse monoclonal antibody against THC (Gold Conjugate), BSA-THC (Test Line) and phosphate buffer and Tris buffer. The cutoff of the test is 50 ng/ml of THC (11-nor-9-tetrahydrocannabinol-9-carboxylic acid).

The THC test cassette has a letter T and C as "Test Line" and "Control Line" on the surface of the case. Both the "Test Line" and the "Control Line" in the result window are not visible before applying any samples. The "Control Line" is used for procedural control. The control line should always appear if the test procedure is performed properly and the test reagents of are working correctly.

MATERIALS PROVIDED

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

1. THC test cassette.
2. Disposable sample dropper.
3. 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 dropper 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

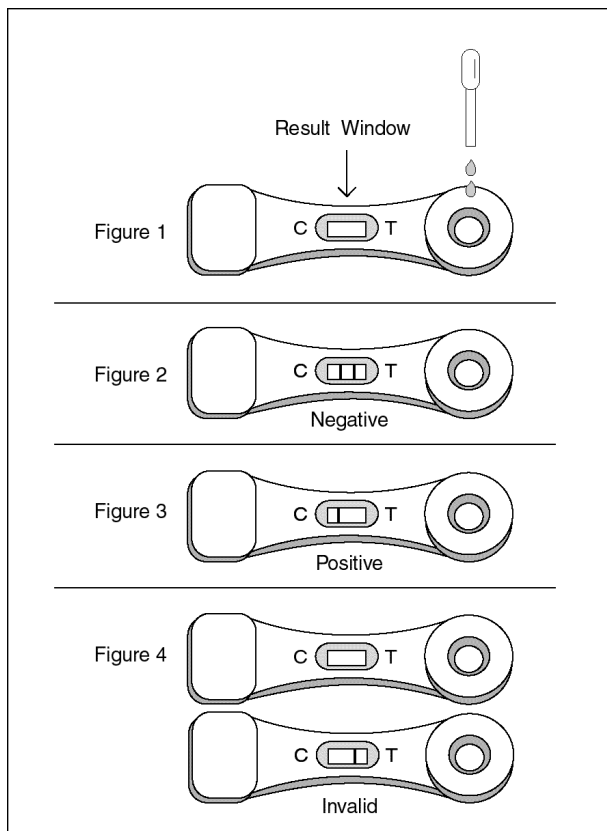
1. Fresh urine specimens do not require any special handling or pretreatment.
2. Specimens should be collected in a clean glass or plastic container.
3. If testing will not be performed immediately, specimens should be refrigerated.
4. Specimens should be brought to room temperature before testing.
5.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

PROCEDURE OF THE TEST

1. Remove the test disk from the foil packet, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk. Squeeze 2 drops of specimen into the sample well (See following Figures).
3. Interpret the test results at 3 to 5 minutes.

INTERPRETATION OF RESULTS

1. As the test kit begins to work, a purple band will appear at the left section of the result window to show that the Control Line is working properly.
2. The right section of the result window indicates the test results. If another purple band appears at the right section of the result window, this band is the Test Band.



NEGATIVE: TWO COLOR BANDS

The appearance of two purple bands within the result window indicates a negative test result. No THC above the cut-off level has been detected. **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.**

POSITIVE: ONE COLOR BAND

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

The urine specimen should be confirmed with a more specific alternative method such as gas chromatography/mass spectrometry, before a positive determination is made.

INVALID:

A distinct purple band should always appear in the left section of the result window. The test is invalid if no purple band forms in the left section of the result window (Control Line).

Note. A very faint band in the right section of the result window, visible in 5 minutes, indicates that the amount of THC in the sample is near or below the cut-off level of the test. The urine specimen should be retested, or confirmed with a more specific alternative method such as gas chromatography/mass spectrometry, before a positive determination is made.

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-minute 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 in 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 contain 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 and 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.