Marijuana
Card Test

INTENDED USE
The One-Step Marijuana (THC) Test is a rapid qualitative, competitive binding, immunoassay for detection of tetrahydrocannabinol (THC) metabolites in urine. The test provides only presumptive data that should be confirmed by other methods such as gas chromatography / mass spectrometry (GC/MS).[1-4] Positive results should be justified with compelling clinical evidence and professional judgment.

SUMMARY AND EXPLANATION OF THE TEST
The One-Step Marijuana Test employs a unique monoclonal antibody set to selectively identify THC metabolites in urine with a high degree of sensitivity. Marijuana is considered to be a major drug of abuse. After smoking or oral administration, the major psychoactive compound, tetrahydrocannabinol, is extensively metabolized before excretion.[7]The excretion half-life of cannabinoid metabolites in urine, estimated by different techniques, ranges from one to ten days.[1] For an initial immunoassay result, a cut-off value of 50 ng/ml total cannabinoid metabolites is required by the mandatory reference guidelines from the U.S. Department of Health and Human Services.* All presumptive positive results must be confirmed at a cut-off concentration of 15 ng/ml of 11-nor-19-tetrahydrocannabinol-9- carboxylic acid.
The One-step Marijuana Test is an easy, fast, and visually read screening test that does not require instrumentation.

PRINCIPLE OF THE TEST
The One-Step Marijuana Test includes a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a THC derivative immobilized on the membrane for binding with antibody-dye conjugate. THC or its metabolites, if present in the test sample at a concentration of 50 ng/ml or higher will block the combining sites of dye-conjugated anti-THC antibodies. Thus, the conjugate will not be captured by THC derivative immobilized in the test zone (T) of the membrane and a visible pink-rose band will not form in the test zone. The pink-rose test band will form in the test zone if the drug level in the sample is below the detection level of 50 ng/ml. Test samples, regardless of drug content, will produce a pink-rose band in the control zone as dye conjugate binds to the immobilized reagent to demonstrate that the assay is functioning correctly.

REAGENTS AND MATERIALS PROVIDED
1. Testing Device: Each device contains membrane-immobilized reagents in a protein matrix containing sodium azide.
2. Transfer Pipette, (sealed inside the foil pouch)

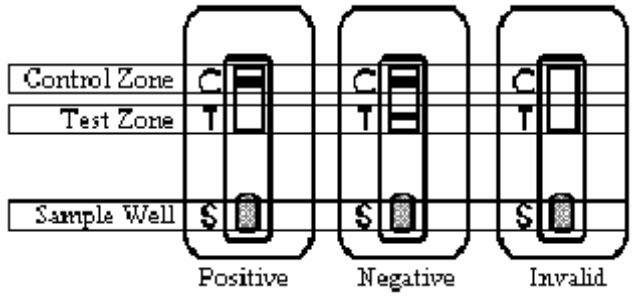
WARNINGS AND PRECAUTIONS
1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Urine specimens may be infectious: properly handle and dispose of all used reaction devices in a biohazard container.

STORAGE AND STABILITY
Store the test kit below 28°C; do not freeze. Refer to the expiration date for stability.

SAMPLE COLLECTION AND PREPARATION
Collect a urine sample in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2 - 8°C) and stored up to forty-eight hours. For longer storage, samples should be frozen (-20°C or below). Frozen or refrigerated samples must be brought to room temperature before testing.
Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE
1. Bring the test components to room temperature before opening the pouch.
2. Remove the Test Device from the foil wrapper by tearing along the "notch" and place it on a flat surface.
3. Fill the Transfer Pipette with urine sample. Holding the dropper vertically, dispense two to three (2 - 3) full drops of urine (without air bubble) into the sample well (S).
4. Read the test result at five minutes.
IMPORTANT*: In order to prevent incorrect readings, do not interpret test results after more than ten minutes.*

INTERPRETATION OF RESULTS



Positive: One pink-rose band appears in the control zone (C) and no band appears in the test zone (T). A positive result indicates that THC level is 50 ng/ml or higher.
Negative: Two pink-rose color band appear. one in the control region and one in the test region. A negative result indicates that THC level is below the detection sensitivity of 50 ng/ml.
Invalid: If there are no distinct color bands visible in both the test zone and the control zone or if there is a visible band in the test zone but not in the control zone, then the test is invalid. In this instance, retesting of the specimen is recommended.

QUALITY CONTROL
1. An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.
2. The use of external control procedures is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE PROCEDURE
1. This product is designed to be used for the detection of THC in human urine only.
2. Although the test is very accurate in detecting the THC level in urine, interfering substances in the test sample can cause false result.
3. The test is a qualitative screening assay and is not suggested for determining quantitative THC levels in urine or the level of intoxication.
4. Adulterants, such as bleach or other strong oxidizing agents, if present in urine specimens, can produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

PERFORMANCE CHARACTERISTICS
1. *Sensitivity:* The Test has been designed to detect the total cannabinoid metabolites in urine at a detection sensitivity level of 50 ng/ml, which is suggested for the immunoassay method.
2. *Specificity:* The Test will selectively detect cannabinoid metabolites in urine.

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The specificity was tested by adding the following drug, drug metabolites, and other compounds to drug-free urine samples. There is no interference by these substances at a 10 ug/ml concentration in urine:

1. d,1 Amphetamine
2. (+) Methamphetamine
3. (±) Deoxyephedrine
4. (-) Deoxyephedrine
5. Phencyclidine
6. Phenobarbital
7. Morphine

REFERENCES

1. Johansson, E., Gillespie, H.K., Halldin, M.M.J. *Anal. Toxicol*., 14: 176-180 (1990).
2. El Sohly, M.A., Jones, A.B., El Sohly, H.N.J. *Anal, Toxicol*., 14: 277-279 (1990).
3. Foltz, R.L., Sunshine, I.J. *Anal. Toxicol*., 14: 375-378 (1990).
4. Wimbish, G.H., Johnson, K.D.J. *Anal. Toxicol*., 14: 292-295 (1990)
5. Nakamura. G.R., Meeks, R.D., Stall, W.J.J. *Forensic Sci*. 35(4): 792-796 (1990).
6. Jenkins, A.J., Milis, L.C., Darwin, W.D., Huestis, M.A., Cone, E.J., Mitchell, J.M.J. *Anal. Toxicol*., 17: 292-298 (1993).
7. Hollister, L.E., Kanter, S.L., Board, R.D., Green, D.E. *Res. Com. Chem. Pathol. Pharmacol.*, 8: 579-584 (1974).
8. *Federal Register* 53: 11970-11983 (1988).