One Step Drug of Abuse Test

(Dipcard)

This Instruction Sheet is for testing of any combination of the following drugs: THC20/THC50/ THC100/ THC200
A rapid, one step screening test for the simultaneous, qualitative detection of Marijuana (11-nor-Δ^9-THC-9-COOH metabolite) in human urine.

For Forensic Use Only

INTENDED USE

The ***One Step Drug of Abuse Test*** is a lateral flow chromatographic immunoassay for the qualitative detection of Marijuana (11-nor-Δ^9-THC-9-COOH metabolite) in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Marijuana (THC 200)	11-nor-Δ^9-THC-9-COOH	200 ng/mL
Marijuana (THC 100)	11-nor-Δ^9-THC-9-COOH	100 ng/mL
Marijuana (THC 50)	11-nor-Δ^9-THC-9-COOH	50 ng/mL
Marijuana (THC 20)	11-nor-Δ^9-THC-9-COOH	20 ng/mL

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[1] Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The ***One Step Drug of Abuse Test*** is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of Marijuana (11-nor-Δ^9-THC-9-COOH metabolite) in human urine without the use of an instrument.

MARIJUANA (THC 200)
THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking 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-Δ^9-tetrahydrocannabinol-9-carboxylic acid (11-nor-Δ^9-THC-9-COOH).
The THC 200 assay contained within the ***One Step Drug of Abuse Test*** yields a positive result when the concentration of 11-nor-Δ^9-THC-9-COOH in urine exceeds 200 ng/mL.

MARIJUANA (THC 100)
See MARIJUANA (THC 200) for the summary.
The THC 100 assay contained within the ***One Step Drug of Abuse Test*** yields a positive result when the concentration of 11-nor-Δ^9-THC-9-COOH in urine exceeds 100 ng/mL.

MARIJUANA (THC 50)
See MARIJUANA (THC 200) for the summary.
The THC 50 assay contained within the ***One Step Drug of Abuse Test*** yields a positive result when the concentration of 11-nor-Δ^9-THC-COOH in urine exceeds 50 ng/mL.

MARIJUANA (THC 20)
See MARIJUANA (THC 200) for the summary.
The THC 20 assay contained within the ***One Step Drug of Abuse Test*** yields a positive result when the concentration of 11-nor-Δ^9-THC-COOH in urine exceeds 20 ng/mL.

PN: Y03111392021

PRINCIPLE

The ***One Step Drug of Abuse Test*** is an immunoassay based on the principle of competitive binding. Drug which may be present in the urine specimen compete against its respective drug conjugate for binding sites on its specific antibody.
During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.
A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.
To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Marijuana.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The test dipcard should remain in the sealed pouch until use.
- The test is for single use.
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood[8,9], the use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test dipcard and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test dipcard must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided
• Test dipcard • Desiccants • Package insert
Materials Required But Not Provided
• Specimen collection container • Disposable gloves • Timer

DIRECTIONS FOR USE

Allow the test dipcard, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1) Remove the test dipcard from the foil pouch.
2) Remove the cap from the test dipcard. Label the dipcard with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic dipcard.
4) Replace the cap over the absorbent tip and lay the dipcard flatly on a non-absorptive clean surface.
5) Read results at 5 minutes. **DO NOT INTERPRET RESULTS AFTER 10 MINUTES.**

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
NEGATIVE: Two lines appear. * One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.
POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test dipcard. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The ***One Step Drug of Abuse Test*** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [3,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. A positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
4. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.
6. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

In the comparison study, the ***One Step Drug of Abuse Test*** was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types list on the following table. Clinical specimens were quantified by GC/MS analysis before testing.

The following results are tabulated from these clinical studies:
% Agreement with GC/MS

	THC50	THC20
Positive Agreement	96%	>99%
Negative Agreement	>99%	>99%
Overall Agreement	98%	>99%

Analyte	THC50		THC20	
	Pos	Neg	Pos	Neg
Negative Samples	0	0	0	40
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	0	15	0	3
Near Cut-off Positive Samples [between cut-off and 150% of cut-off]	23	1	3	0
Positive Samples [>150% of cut-off]	1	0	47	0
Agreement with GC/MS	96%	>99%	>99%	>99%