

SureStep™ THC Marijuana Test Device (Urine) Package Insert

One Step

THC Marijuana Test Device (Urine) Package Insert

English

A rapid, one step test for the qualitative detection of THC metabolites in human urine. For medical and other professional *in vitro* diagnostic use only.

INTENDED USE

The THC One Step Marijuana Test Device (Urine) is a rapid chromatographic immunoassay for the detection of 11-nor- Δ^2 -THC-9 COOH (THC metabolite) in human urine at a cut-off concentration of 50 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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

SUMMARY

THC (Δ^2 -tetrahydrocannabinol) is the primary active ingredient in cannabinoids (Marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. Users may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking Marijuana 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^2 -tetrahydrocannabinol-9-carboxylic acid (Δ^2 -THC-COOH).

The THC One Step Marijuana Test Device (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Marijuana in urine. The THC One Step Marijuana Test Device (Urine) yields a positive result when the concentration of Marijuana in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The THC One Step Marijuana Test Device (Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Marijuana, if present in the urine specimen below 50 ng/mL, will not saturate the binding sites of the antibody coated particles in the test. The antibody coated particles will then be captured by immobilized THC conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Marijuana level is above 50 ng/mL because it will saturate all the binding sites of anti-Marijuana antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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 mouse monoclonal anti-Marijuana antibody-coupled particles and Marijuana-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test 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 centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C 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 before testing.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Package insert

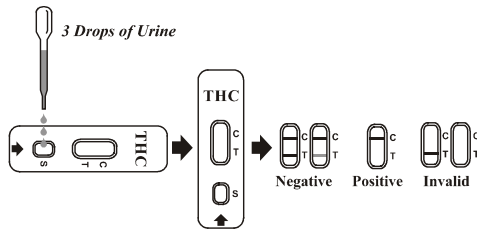
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 100 μ L) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: * **Two lines appear.** One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Marijuana concentration is below the detectable level (50 ng/mL).

* **NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: **One colored line appears in the control line region (C).** No line appears in the test line region (T). This positive result indicates that the Marijuana concentration is above the detectable level (50 ng/mL).

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 with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The THC One Step Marijuana Test Device (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method.^{1,2}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

A three way side-by-side comparison was conducted using the THC One Step Marijuana Test Device (Urine) and a leading commercially available THC rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 50 ng/mL. 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other THC Rapid Test		Total Results
	Positive	Negative	
THC One Step Test Device	Results Positive	143	143
	Results Negative	0	157
	Total Results	143	157
% Agreement	>99%	>99%	>99%

When compared to GC/MS at 50 ng/mL, the following results were tabulated:

Method	GC/MS		Total Results
	Positive	Negative	
THC One Step Test Device	Results Positive	119	143
	Results Negative	3	154
	Total Results	122	178
% Agreement	98%	87%	91%

When compared to GC/MS at 25 ng/mL, the following results were tabulated:

Method	GC/MS		Total Results
	Positive	Negative	
THC One Step Test Device	Results Positive	137	143
	Results Negative	4	153
	Total Results	141	159
% Agreement	97%	96%	97%

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid at the following concentrations: 0 ng/mL, 25 ng/mL, 37.5 ng/mL, 50 ng/mL, 62.5 ng/mL, and 75 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

11-nor- Δ^2 -THC-9 COOH Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
37.5	-25%	30	10	20
50	Cut-off	30	4	26
62.5	+25%	30	3	27
75	+50%	30	0	30

Analytical Specificity

The following table lists compounds and their respective concentrations in urine that yield a positive result in the THC One Step Marijuana Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Cannabinol	20,000
11-nor- Δ^2 -THC-9 COOH	30
11-nor- Δ^2 -THC-9 COOH	50
Δ^2 -THC	15,000
Δ^2 -THC	15,000

Precision

A study was conducted at three physicians' offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid, 25% 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid above and below the 50 ng/mL cut-off was provided to each site. The following results were tabulated:

11-nor- Δ^2 -THC-9 COOH Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14	1	15	0	15	0
25	15	15	0	15	0	15	0
37.5	15	8	7	14	1	8	7
62.5	15	0	15	0	15	0	15
75	15	0	15	0	15	0	15

Effect of Urinary Specific Gravity

Twenty-six urine specimens of normal, high, and low specific gravity ranges were spiked with 25 ng/mL and 75 ng/mL of 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid. The THC One Step Marijuana Test Device (Urine) was tested in duplicate using the twenty-six neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with 11-nor- Δ^2 -Tetrahydrocannabinol-9-carboxylic acid to 25 ng/mL and 75 ng/mL. The spiked, pH-adjusted urine was tested with the THC One Step Marijuana Test Device (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Marijuana positive urine. The following compounds show no cross-reactivity when tested with the THC One Step Marijuana Test Device (Urine) at a concentration of 100 μ g/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Deoxycorticosterone	(+) 3,4-Methylenedioxyamphetamine	Prednisolone
Acetophenetidin	Dextromethorphan	(+) 3,4-Methylenedioxyprocaine	Prednisone
N-Acetylprocainamide	Diazepam	Methamphetamine	Promazine
Acetylsalicylic acid	Diclofenac	Methylphenidate	Promethazine
Aminopyrine	Diffusalin	Methyprylon	D,L-Propranolol
Amitypyline	Digoxin	Morphine-3- β -D-glucuronide	D-Propoxyphene
Amobarbital	Diphenhydramine	Nalidixic acid	D-Pseudoephedrine
Amoxicillin	Doxylamine	Naloxone	Quinidine
Ampicillin	Egonine hydrochloride	Naloxone	Quinine
L-Ascorbic acid	Egonine methylester	Naloxone	Ranitidine
D,L-Amphetamine	(-)- ψ -Ephedrine	Naltrexone	Salicylic acid
L-Amphetamine	Erythromycin	Naproxen	Secobarbital
Apomorphine	β -Estradiol	Niacinamide	Serotonin (5-Hydroxytryptamine)
Aspartame	Estrone-3-sulfate	Nifedipine	Sulfamethazine
Atropine	Ethyl-p-aminobenzoate	Nicothine	Sulindac
Benzlic acid	Fenpropfen	Norethindrone	Temazepam
Benzic acid	Furosemide	Orphenadrine	Tetracycline
Benzoylcegonine	Genisteic acid	D-Norpropoxyphene	Tetrahydrocortisone,
Benzphetamine	Hemoglobin	Noscapine	3-Acetate
Bilirubin	Hydralazine	D,L-Octopamine	Tetrahydrocortisone
(\pm)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	3 (β -D-glucuronide)
Caffeine	Hydrocodone	Oxazepam	Tetrahydrozoline
Cannabidiol	Hydrocortisone	Oxycodone	Thebaine
Chloralhydrate	O-Hydroxyhippuric acid	Oxycodone	Thiamine
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thioridazine
Chloridiazepoxide	Ibuprofen	Phenacetin	D, L-Thioxine
Chlorothiazide	Imipramine	Phenazone	Tolbutamide
(\pm) Chlorpheniramine	Iproniazid	Phenobarbital	Triamterene
Chlorpromazine	(\pm) - Isoprotrenol	Phentermine	Trifluoperazine
Chlorquine	Isosuxrine	Phenylephrine	Trimethoprim
Cholesterol	Ketamine	Methadone	Tripropiramine
Clomipramine	Ketoprofen	Methoxyphenamine	Triptamine
Clonidine	Labeltal		D, L-Tryptophan
Cocaine hydrochloride	Levorphanol		Tyramine
Codeine	Loperamide		D, L-Tyrosine
Cortisone	Maprotiline		Uric acid
(-) Cotinine	Meprobamate		Verapamil
Creatinine	Methadone		Zomepirac
	Methoxyphenamine		

BIBLIOGRAPHY

- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*, 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #

	Innovacon, Inc. 4106 Sorrento Valley Boulevard San Diego, CA 92121, USA			MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
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