

One Step Marijuana Test Strip (Urine) Package Insert **REF 1190-S**

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

The THC One Step Marijuana Test Strip (Urine) is a rapid chromatographic immunoassay for the detection of 11-nor-Δ°-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 (Δ⁹-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. 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 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^{0} -tetrahydrocannabinol-9carboxylic acid (Δ9-THC-COOH).

The THC One Step Marijuana Test Strip (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 Strip (Urine) yields a positive result when the concentration of Marijuana in urine exceeds 50 ng/mL. This is the suggested screening cutoff for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The THC One Step Marijuana Test Strip (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 strip. The antibody coated particles will then be captured by immobilized Marijuana 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.

The test strip contains mouse monoclonal anti-Marijuana antibody-coupled particles and Marijuanaprotein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- · For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test strip 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 strip 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 strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assav

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

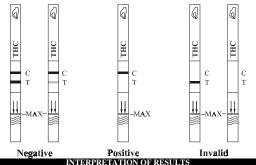
· Test strips · Package insert

· Specimen collection container Timer

DIRECTIONS FOR USE

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

- 1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
- 2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing it. See the illustration below.
- 3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the result after 10 minutes.



(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 strip. 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 practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- 1. The THC One Step Marijuana Test Strip (Urine) provides only a quantitative, 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.
- 2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 3. 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.
- 4. A positive result does not indicate level of intoxication, administration route or concentration in urine.
- 5. 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 Strip (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°-Tetrahydrocannabinol-9-carboxylic acid. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other THC	Total Results	
THC One Step	Results	Positive	Negative	Total Results
Test Strip	Positive	140	0	140
	Negative	3	157	160
Total Results		143	157	300
% Agreement		98%	>99%	99%

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

Method		GC	Total Results			
THC One Step	Results	Positive	Negative	Total Results		
Test Strip	Positive	118	22	140		
	Negative	4	156	160		
Total Re	esults	122	178	300		
% Agreement		97%	88%	91%		

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

Method		GC	Total Results	
THC One Step	Results	Positive	Negative	Total Results
Test Strip	Positive	135	5	140
rest Strip	Negative	6	154	160
Total Results		141	159	300
% Agreement		96%	97%	96%

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor-Δ9-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-∆°-THC-9 COOH	Percent of Cut-off	n	Visual Result		
	Concentration (ng/mL)	refeelt of cut-off		Negative	Positive	
	0	0	30	30	0	
Π	25	-50%	30	30	0	
Π	37.5	-25%	30	12	18	
	50	Cut-off	30	1	29	
	62.5	+25%	30	1	29	
	75	+50%	30	0	30	
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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 Strip (Urine) at 5 minutes.

Concentration (ng/mL) Compound Cannabinol 20.000 11-nor-Δ⁸- THC-9 COOH 11-nor-Δ9- THC-9 COOH 15,000 Λ⁹- THC 15,000

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-Δ9-Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor-Δ°-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-∆9-THC-9 COOH	n	Site A		Site B		Site C	
Concentration (ng/mL)	per Site	1	+	1	+	1	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	Λ	15	Λ	15	Λ	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°-Tetrahydrocannabinol-9-carboxylic acid. The THC One Step Marijuana Test Strip (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° -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 Strip (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 Strip (Urine) at a concentration of 100 µg/mL.

	Non Cross-		
4-Acetamidophenol	Deoxycorticosterone	(+) 3,4-Methylenedioxy-	Prednisolone
Acetophenetidin	Dextromethorphan	amphetamine	Prednisone
N-Acetylprocainamide	Diazepam	(+) 3,4-Methylenedioxy-	Procaine
Acetylsalicylic acid	Diclofenac	methamphetamine	Promazine
Aminopyrine	Diflunisal	Methylphenidate	Promethazine
Amitryptyline	Digoxin	Methyprylon	D,L-Propanolo
Amobarbital	Diphenhydramine	Morphine-3-	D-Propoxyphe

ocaine Acety omazine Amir omethazine Amit L-Propanolol Amol D-Propoxyphene D-Pseudoephedrin Amoxicillin Doxylamine Econine hydrochloride Ampicillin Nalidixic acid Oninidine L-Ascorbic acid Ecgonine methylester Nalorphine D.L.-Amphetamine (-)-w-Enhedrine Naloxone Ranitidine Naltrexone Apomorphine β-Estradiol Secobarbital Naproxen Estrone-3-sulfate Viacinamide Serotonin (5-Hydroxytyramine) Aspartame Atropine Ethyl-p-aminobenzoate Nifedipine Sulfamethazine Benzilic acid Norcodein Sulindac Fenoprofen Norethindrone Temazepam Benzoic acid Furosemide Benzoylecgonine Gentisic acid D-Norpropoxyphene Tetracycline Hemoglobin Tetrahydrocortisone Benzphetamine Noscapine Bilirubin Hydralazine D,L-Octopamir 3-Acetate (±)-Brompheniramine Hydrochlorothiazide Oxalic acid Tetrahydrocortisone Oxazepam Caffeine Hydrocodone 3-(B-D-glucuronide) Cannabidiol Oxolinic acid Tetrahydrozoline Hydrocortisone Chloralhydrate O-Hydroxyhippuric acid Oxycodone Thebaine Chloramphenicol 3-Hydroxytyramine Oxymetazoline Thiamine Chlordiazepoxide Ibuprofen p-Hvdroxv-Thioridazine D, L-Thyroxine Chlorothiazide Imipramine methamphetamin (+) Chlorpheniramine Inroniazid Papaverine Tolbutamine (±) - Isoproterenol Penicillin-G Triamterene Chlorpromazin Chlorquine Isoxsuprine Ketamine Pentazocine Trifluoperazine Cholesterol Pentobarbital Trimethoprim Clomipramine Ketoprofen Perphenazine Triminramine Clonidine Labetalol Phencyclidine Tryptamine D, L-Tryptophan Cocaine hydrochloride Levorphanol Phenelzine Codeine Loperamide Phenobarbital D, L-Tyrosine Cortisone Maprotiline Phentermine (-) Cotinine Menrohamate L-Phenylenhrine Methadone Creatinine β-Phenylethylamine Verapamil

Methoxyphenamine BIBLIOGRAPHY

- 1. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986
- 2. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982: 48

Index of Symbols

1	Storage Temperature	***	Manufacturer	2	Do not reuse
LOT	Lot Code	EC REP	Authorized Representative	IVD	For in vitro diagnostic use
\sum	Expiration	\triangle	Caution, see instructions	REF	Catalog No.





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