



**One Step
Marijuana Test Strip (Urine)
Package Insert**

REF R-1102 English

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

INTENDED USE

The THC One Step Marijuana Test Strip (Urine) is a rapid chromatographic immunoassay for the detection of 11-nor- Δ^9 -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^9 -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^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -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 cut-off 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.

REAGENTS

The test strip contains mouse monoclonal anti-Marijuana antibody-coupled particles and Marijuana-protein 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 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

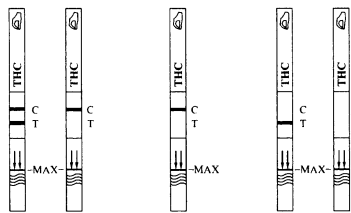
Materials Provided

- Test strips
 - Package insert
- Material Required But Not Provided
 - Timer
- Specimen collection container

DIRECTIONS FOR USE

Allow the test strip, 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 strip from the sealed pouch and use it as soon as possible.
- 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.
- 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.



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).

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 the 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

- 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.^{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 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 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^9 -Tetrahydrocannabinol-9-carboxylic acid. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other THC Rapid Test			Total Results
	Results	Positive	Negative	
THC One Step 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/MS			Total Results
	Results	Positive	Negative	
THC One Step Test Strip	Positive	118	22	140
	Negative	4	156	160
Total Results		122	178	300
% Agreement		97%	88%	91%

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

Method	GC/MS			Total Results
	Results	Positive	Negative	
THC One Step Test Strip	Positive	135	5	140
	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- Δ^9 -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^9 -THC-9 COOH Concentration (ng/mL)	Percent of Cut-off	n	Visual Results	
			Negative	Positive
0	0%	30	30	0
25	-50%	30	30	0
37.5	-25%	30	12	18
50	Cut-off	30	1	29
62.5	+25%	30	0	29
75	+50%	30	1	29

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.

Compound	Concentration (ng/mL)
Cannabinol	20,000
11-nor- Δ^9 -THC-9 COOH	30
11-nor- Δ^8 -THC-9 COOH	50
Δ^9 -THC	15,000
Δ^8 -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^9 -Tetrahydrocannabinol-9-carboxylic acid, 25% 11-nor- Δ^9 -Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor- Δ^9 -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^9 -THC-9 COOH Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	0	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	15	0	15	0	15	0
75	15	15	0	15	0	15	0

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^9 -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^9 -Tetrahydrocannabinol-9-carboxylic acid to 25 ng/mL and 75 ng/mL. The spiked, aliquoted 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 ng/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Deoxy corticosterone	(-)-3,4-Methylenedioxyamphetamine	Prednisolone
Acetophenidin	Dexamethorphan	(+)-3,4-Methylenedioxyamphetamine	Progesterone
Acetylsalicylic acid	Diazepam	methamphetamine	Promazine
Amilorifone	Diflunisal	Methylphenidate	Promethazine
Amiriprylone	Digoxin	Morphine	D,L-Propranolol
Amobarbital	Diphenhydramine	Morphine-3- β -D-glucuronide	D-Propoxyphene
Amoxicillin	Doxylamine	Nalidixic acid	Quinidine
Ampicillin	Egonone hydrochloride	Naloxone	Quinine
L-Ascorbic acid	Egonone methyl ester	Naltrexone	Rantidine
DL-Amphetamine	(-)- β -Ephedrine	Naloxone	Salicylic acid
L-Amphetamine	Erythromycin	Naloxone	Secobarbital
Apoporphine	β -Estradiol	Naracetamol	Serotonin (5-Hydroxytryptamine)
Aspartame	Estrone-3-sulfate	Niacinamide	Sulfamethiazole
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Sulfonamide
Benzoic acid	Fenofenone	Nocodol	Sulindac
Benzoic acid	Furosemide	Norethindrone	Tamoxifen
Benzocaine	Furosemide	Di-Norpropoxyphene	Tetracycline
Benzphetamine	Genisteic acid	Nescapine	Tetrahydrocortisone
Bilirubin	Hydralazine	DL-Octopamine	3-Acetate
(-)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	Tetrahydrocortisone
Caffeine	Hydrocodone	Oxazepam	3-(β -D-glucuronide)
Cannabidiol	Hydrocortisone	Oxolinic acid	Tetrahydrozoline
Chloralhydrate	O-Hydroxyhippuric acid	Oxytocin	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thiamine
Chloridiazepoxide	Ibuprofen	p-Hydroxy-methamphetamine	Thioctic acid
Chlorothiazide	Imipramine	Iproniazid	D, L-Thyroxine
(-)-Chlorpheniramine	Ironizid	Papaverine	Tolbutamide
Chlorpromazine	(-)-Isoproterenol	Penicillin-G	Triamterene
Chloquin	Keptone	Pentazocine	Trifluoperazine
Cholesterol	Isosuprine	Pentazocine	Trimethoprim
Chlorpromazine	Ketoprofen	Perphenazine	Trimipramine
Clonidine	Labelalol	Phencyclidine	Tryptamine
Cocaine hydrochloride	Levorphanol	Phenazine	D, L-Tryptophan
Codine	Loperamide	Phenobarbital	Tyramine
Cortisone	Maprotiline	Phentermine	D, L-Tyrosine
(-)-Cocaine	Meprobamate	L-Phenylephrine	Uric acid
Creatinine	Methadone	β -Phenylethylamine	Verapamil
	Methoxyphenamine	Phenylpropanolamine	Zonipril

BIBLIOGRAPHY

- Hawks RL, CN Chang. *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

Attention, see instructions for use

Tests per kit

Manufacturer

For in vitro diagnostic use only

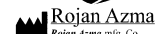
Use by

Do not reuse

Store between 2-30°C

LOT Lot Number

ISO, CE, GMP



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