THC Rapid Test Cassette
(Urine)
Package Insert

ACRO BIOTECH, INC

For professional in vitro diagnostic use only.
A rapid test for the qualitative detection of Marijuana in human urine.

INTENDED USE

The THC Rapid Test Cassette (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 50ng/mL.
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. 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^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).
The THC Rapid Test Cassette (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 Rapid Test Cassette yields a positive result when the concentration of Marijuana in urine exceeds 50ng/ml. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

THC Rapid Test Cassette (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 50ng/ml, will not saturate the binding sites of the antibody coated particles in the cassette. 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 50ng/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-THC antibody-coupled particles and THC-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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided

- Test cassettes
- Droppers
- Package insert

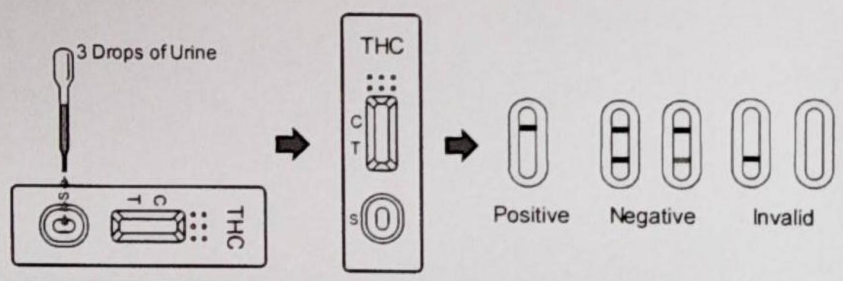
Materials Required But Not Provided

- Specimen collection container
- Timer

INSTRUCTIONS

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

1. *Bring the pouch to room temperature before opening it.* Remove the test cassette from the sealed pouch and **use it within one hour.**
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120 µL) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the color line(s) to appear. The result should be read 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 color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the Marijuana concentration is below the detectable level of 50ng/ml.

***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of 11-nor-Δ9 -THC-9 COOH (THC metabolite) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered negative.

POSITIVE: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the Marijuana concentration is above the detectable level of 50ng/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 cassette. If the problem persists, discontinue using the test cassette immediately and contact your local distributor.

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 and correct procedural technique.
Control standards are not supplied with this test cassette; 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

1. THC Rapid Test Cassette (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]
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 indicates presence of the drug or its metabolites but 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.
6. Test does not distinguish between drugs of abuse and certain medications.

EXPECTED VALUES

This negative result indicates that the Marijuana concentration is below the detectable level of 50ng/mL. Positive result means the concentration of Marijuana is above the level of 50ng/mL. The THC Rapid Test Cassette has a sensitivity of 50ng/mL.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using The THC Rapid Test Cassette and a commercially available THC rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated.

Method		Other THC Rapid Test		Total Results
THC Rapid Test Cassette	Results	Positive	Negative	
	Positive	41	0	41
	Negative	0	59	59
Total Results		41	59	100
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The THC Rapid Test Cassette and GC/MS at the cut-off of 50ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated.

Method		GC/MS		Total Results
THC Rapid Test Cassette	Results	Positive	Negative	
	Positive	92	3	95
	Negative	2	153	155
Total Results		94	156	250
% Agreement		97.9%	98.1%	98.0%

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor-Δ^9-Tetrahydrocannabinol-9-COOH at the following concentrations: 0ng/mL, 25ng/mL, 37.5ng/mL, 50ng/mL, 62.5ng/mL 75ng/mL and 150ng/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	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	-50%	30	30	0
37.5	-25%	30	26	4
50	Cut-off	30	14	16
62.5	+25%	30	3	27
75	+50%	30	0	30
150	3X	30	0	30

Analytical Specificity

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

Compound	Concentration (ng/mL)
Cannabinol	35,000
11-nor-Δ^8-THC-9 COOH	30
11-nor-Δ^9-THC-9 COOH	50
Δ^8-THC	17,000
Δ^9-THC	17,000

Precision

A study was conducted at three hospitals by laypersons 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-Δ9-Tetrahydrocannabinol-9-carboxylic acid, 25% 11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid above and below the cut-off, and 50% 11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid above and below the 50ng/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	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	9	1	8	2	9	1
62.5	10	1	9	1	9	2	8
75	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 25ng/mL and 75ng/mL of 11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid. The THC Rapid Test Cassette (Urine) was tested in duplicate using the fifteen 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-Δ9-Tetrahydrocannabinol-9-carboxylic acid to 25ng/mL and 75ng/mL. The spiked, pH-adjusted urine was tested with the THC Rapid Test Cassette (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 THC Rapid Test Cassette (Urine) at a concentration of 100µg/ml.

Non Cross-Reacting Compounds

4-Acetamidophenol	Deoxycorticosterone	(+) 3,4-Methylenedioxy-amphetamine	Prednisolone
Acetophenetidin	Dextromethorphan	(+) 3,4-Methylenedioxy-methamphetamine	Prednisone
N-Acetylprocainamide	Diazepam	Morphine-3-β-D-glucuronide	Procaine
Acetylsalicylic acid	Diclofenac	Nalidixic acid	Promazine
Aminopyrine	Diflunisal	Nalorphine	Promethazine
Amitryptyline	Digoxin	Naloxone	D,L-Propanolol
Amobarbital	Diphenhydramine	Naltrexone	D-Propoxyphene
Amoxicillin	Doxylamine	Naproxen	D-Pseudoephedrine
Ampicillin	Ecgonine hydrochloride	Niacinamide	Quinidine
L-Ascorbic acid	Ecgonine methylester	Nifedipine	Quinine
D,L-Amphetamine	(-)-ψ-Ephedrine	Norcodein	Ranitidine
L-Amphetamine	Erythromycin	Norethindrone	Salicylic acid
Apomorphine	β-Estradiol	D-Norpropoxyphene	Secobarbital
Aspartame	Estrone-3-sulfate	Noscapine	Serotonin (5-Hydroxytyramine)
Atropine	Ethyl-p-aminobenzoate	D,L-Octopamine	Sulfamethazine
Benzilic acid	Fenoprofen	Oxalic acid	Sulindac
Benzoic acid	Furosemide	Oxazepam	Temazepam
Benzoylecgonine	Gentisic acid	Oxolinic acid	Tetracycline
Benzphetamine	Hemoglobin	Oxycodone	Tetrahydrocortisone, 3-Acetate
Bilirubin	Hydralazine	Oxymetazoline	Tetrahydrocortisone 3 (β-D-glucuronide)
(±)-Brompheniramine	Hydrochlorothiazide	p-Hydroxy-methamphetamine	Tetrahydrozoline
Caffeine	Hydrocodone	Papaverine	Thebaine
Cannabidiol	Hydrocortisone	Penicillin-G	Thiamine
Chloralhydrate	O-Hydroxyhippuric acid	Pentazocine	Thioridazine
Chloramphenicol	3-Hydroxytyramine	Pentobarbital	D, L-Thyroxine
Chlordiazepoxide	Ibuprofen	Perphenazine	Tolbutamine
Chlorothiazide	Imipramine	Phencyclidine	Triamterene
(±) Chlorpheniramine	Iproniazid	Phenelzine	Trifluoperazine
Chlorpromazine	(±) - Isoproterenol	Phenobarbital	Trimethoprim
Chlorquine	Isoxsuprine	Phentermine	Trimipramine
Cholesterol	Ketamine	L-Phenylephrine	Tryptamine
Clomipramine	Ketoprofen	β-Phenylethylamine	D, L-Tryptophan
Clonidine	Labetalol	Phenylpropanolamine	Tyramine
Cocaine hydrochloride	Levorphanol	Prednisolone	D, L-Tyrosine
Codeine	Loperamide	Prednisone	Uric acid
Cortisone	Maprotiline	Procaine	Verapamil
(-) Cotinine	Meprobamate	Promazine	Zomepirac
Creatinine	Methadone	Promethazine	
	Methoxyphenamine	D,L-Propanolol	

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; 488.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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