One Step
Marijuana Test Device
Package Insert

(Catalog Number: 1190-C)

BIOMERICA

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 One Step Marijuana Test Device 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 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 One Step Marijuana Test Device 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 One Step Marijuana Test Device 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 One Step Marijuana Test Device 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 device. 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 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 if the test has been performed properly.

REAGENTS

The test device contains anti-marijuana particles and marijuana conjugate coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device 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 test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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.

PROCEDURE

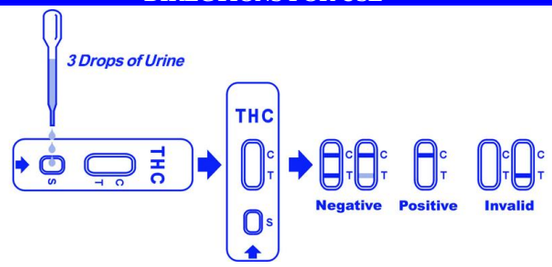
Materials Provided

- Test devices
- Disposable droppers
- Package insert

Materials Required But Not Provided

- Specimen collection container
- External controls
- Timer

DIRECTIONS FOR USE



Allow the test device, 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 device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration above.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

POSITIVE: One red 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 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 device. 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 red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

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

1. The One Step Marijuana Test Device provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. GC/MS is the preferred confirmatory method. [2]
2. The One Step Marijuana Test Device is a qualitative screening assay and cannot determine either the drug concentration in the urine or the level of intoxication.
3. There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.
4. 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.

PERFORMANCE CHARACTERISTICS

Accuracy

A three way side-by-side comparison was conducted using the One Step Marijuana Test Device and a leading commercially available THC rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method		Other THC Rapid Test		Total Results
One Step Test Device	Results	Positive	Negative	
	Positive	143	0	143
	Negative	0	157	157
Total Results		143	157	300

Total Agreement: 100%

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

Method		GC/MS		Total Results
One Step Test Device	Results	Positive	Negative	
	Positive	119	24	143
	Negative	3	154	157
Total Results		122	178	300

Relative Sensitivity: 98% Relative Specificity: 87% Accuracy: 91%

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

Method		GC/MS		Total Results
One Step Test Device	Results	Positive	Negative	
	Positive	137	6	143
	Negative	4	153	157
Total Results		141	159	300

Relative Sensitivity: 97% Relative Specificity: 96% Accuracy: 97%

Point of Care Accuracy

A study was conducted using the same clinical specimens with ten percent (10%) distribution at 25% above and below the 50ng/mL cut-off at three geographically distinct point of care sites to determine the accuracy of the One Step Marijuana Test Device in the hands of point of care user. Forty (40) positive specimens and forty (40) negative specimens were tested on three (3) different lots of each product.
The difference in sensitivity and specificity results obtained by the laboratory professional for the same clinical specimens compared to the results obtained by the point of care (untrained) user was insignificant. At a ninety-five percent (95%) confidence interval, the odds ratio for the point of care user versus the laboratory professional was 1 to 1 for sensitivity and specificity.

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor-Δ9-Tetrahytrocannabinol-9-carboxylic acid at the following concentrations: 75 ng/ml, 62.5 ng/ml, 37.5 ng/ml, 25 ng/ml, and 0 ng/ml. The result demonstrates 100% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

THC Concentration (ng/mL)	Percent Of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
25	50%	30	30	0
37.5	75%	30	10	20
50	Cutoff	30	4	26
62.5	125%	30	3	27
75	150%	30	0	30

Specificity

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

Compound	Concentration (ng/mL)
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
11-nor-Δ^9-THC-9 COOH	50
Δ^8-THC	15,000
Δ^9-THC	15,000

Precision

A study was conducted at 3 geographically distinct physician's offices by untrained operators using 3 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 THC, 25% THC above and below the cut-off and 50% THC above and below the 50 ng/mL cut-off was provided to each site. For the specimens below the -25 % cut-off concentration, the 3 sites demonstrated 98% agreement with each other. For the –25% to +25% cut-off specimens, the 3 sites demonstrated 83% agreement with each other. For specimens above the +25% cut-off concentration, the 3 sites demonstrated 100% agreement with each other. For all results, the 3 sites were found to have a 92% agreement with each other.

Effect of Urinary Specific Gravity

Twenty-six (26) urine samples of normal, high, and low specific gravity ranges were spiked with 25 ng/ml and 75 ng/ml of 11-nor-Δ9-Tetrahytrocannabinol-9-carboxylic acid, respectively. The One Step Marijuana Test Device was tested in duplicate using the twenty-six neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the 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-Tetrahytrocannabinol-9-carboxylic to 25 ng/ml and 75 ng/ml. The spiked, pH-adjusted urine was tested with the One Step Marijuana Test Device in duplicate and interpreted according to the package insert. The results demonstrate that varying ranges of pH does 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 urine not associated with THC. The following compounds show no cross-reactivity when tested with the One Step Marijuana Test Device at a concentration of 100 µg/mL:

Non Cross-Reacting Compounds

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

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

	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, See Instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

Biomerica, Inc.,17571 Von Karman Avenue
Irvine, CA 92614 USA

EC REP

according to IVDD 98/79/ EC
MDSS
Burckhardtstrasse 1
30163 Hannover, Germany