

## Atlas One Step Marijuana Test Device (Urine)

A rapid, one step test for the qualitative detection of THC metabolites in human urine.

**IVD** For In-Vitro diagnostic and professional use only

Store at (2-30° C)

### INTENDED USE

Atlas One Step Marijuana Test Device (Urine) is a rapid chromatographic immunoassay for the detection of 11-nor- $\Delta$ -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.

### INTRODUCTION

THC ( $\Delta$ 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- $\Delta$ -tetrahydrocannabinol-9-carboxylic acid (A9-THC-000H).

Atlas 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. Atlas 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

Atlas 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 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 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.

### MATERIALS

#### Materials Provided

- Test device (Contains mouse monoclonal anti-Marijuana antibody-coupled particles and Marijuana-protein conjugate. A goat antibody is employed in the control line system).
- Disposable dropper.
- Package insert.

#### Materials Required But Not Provided

- Specimen collection container
- Timer

### 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 used 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 Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette 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.

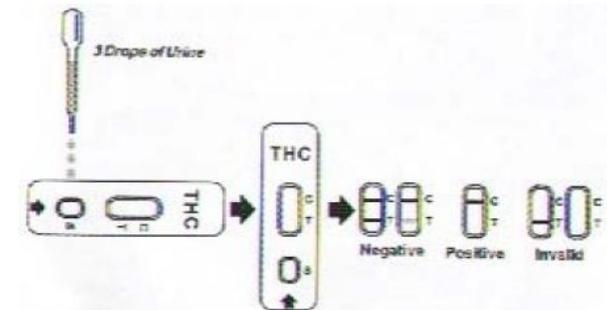
#### Specimen Storage

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

**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. 100 $\mu$ 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.
3. With for the red 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 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 considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

#### LIMITATIONS

1. Atlas One Step Marijuana Test Device (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 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.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

A three way side-by-side comparison was conducted using Atlas One Step Marijuana Test Device (Urine) 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	Results	Other THC Rapid Test		Total Result
		Positive	Negative	
Atlas One Step THC Test Device	Positive	143	0	143
	Negative	0	157	157
Total Results		143	157	300
% Agreement with this Rapid Test.		100%	100%	100%

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

Method	Results	GC/MS		Total Results
		Positive	Negative	
Atlas One Step THC Test Device	Positive	119	24	143
	Negative	3	154	157
Total Results		122	178	300
% Agreement with GC/MS at 50ng/mL		98%	87%	91%

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

Method	Results	GC/MS		Total Results
		Positive	Negative	
Atlas One Step THC Test Device	Positive	137	6	143
	Negative	4	153	157
Total Results		141	159	300
% Agreement with GC/MS at 25ng/mL		97%	96%	97%

##### Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor-9-Tetrahydrocannabinol-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 Cut-off	n	Visual	Result
			Negative	Positive
0	0	30	30	0
25	50%	30	30	0
37.5	75%	30	10	20
50	Cut-off	30	4	26
62.5	125%	30	3	27
75	150%	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- $\Delta^8$ -THC-9 COOH	30
11-nor- $\Delta^9$ -THC-9 COOH	50
$\Delta^8$ -THC	15,000

#### REFERENCES

1. Hawks RL, ON 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



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PPI260A01

Rev B (04.11.2015)

	Product Reference No.		For in-vitro diagnostic use.
	Caution.		Store at 2 - 30°C.
	Read product insert before use.		Number of tests in the pack.
	Lot (batch) number.		Manufacturer.
	Expiry date.		Manufacturer telephone number.
	Manufacturer fax number.		