INTENDED USE

The THC One Step Marijuana Test Device (Urine) is a rapid chromatographic immunoassay for the detection of 11-nor-Δ⁹ -THC-9 COOH (THC metabolite) in human urine at a cut-off concentration of 50 ng/mL.

PRINCIPLE

The THC 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 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 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.

KIT COMPONENTS

- Test Device
- Packaging Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The used testing materials should be discarded in accordance with local, state and/or federal regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The THC Test Device is intended only for use with human urine specimens.
- Collected urine specimens must be put in clear and dry containers. Ensure that a sufficient quantity of the specimen is collected to allow submerging the dipping area of the strip.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing ofspecimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

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 illustration below.
3. Wait 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

POSITIVE RESULT:

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

NEGATIVE RESULT:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

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 good laboratory testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The THC One Step Marijuana Test Device (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.

PERFORMANCE CHARACTERISTICS

Accuracy

A three way side-by-side comparison was conducted using the THC 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		Other THC Rapid Test		Total Results
THC One Step Test Device	Results	Positive	Negative	
	Positive	135	1	136
	Negative	0	201	201
Total Results		135	202	337
% Agreement with this Rapid Test		100%	99.5%	99.7%

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

Method		GC/MS		Total Results
THC One Step Test Device	Results	Positive	Negative	
	Positive	109	21	130
	Negative	2	205	207
Total Results		111	226	337
% Agreement with this Rapid Test		98.2%	90.7%	93.2%

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 Cut-off	n	Visual Result	
			Negative	Positive
0	0	20	20	0
25	50%	20	20	0
37.5	75%	20	9	11
50	Cut-off	20	3	17
62.5	125%	20	3	17
75	150%	20	0	20

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.

Methadone related Compounds	Concentration (ng/ml)
Cannabinol	20,000
11-nor-Δ⁸-THC-9 COOH	30
11-nor-Δ⁹-THC-9 COOH	50
Δ⁸-THC	15,000
Δ-THC	15,000

Precision

A study was conducted at 3 physicians' 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.

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 Device (Urine) at a concentration of 100 µg/mL

Index or Symbols

	Attention, see instructions for use		Tests per Kit		Manufacturer
IVD	For *in vitro*		Use by	2	Do not reuse
	Store between 2 - 30°C	LOT	Lot Number	REF	Catalogue Number

CE

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