MARIJUANA (THC) URINE CASSETTE

HOMEMED

INTENDED USE

The HOMEMED Marijuana (THC) Urine Cassette Test is a rapid visual immunoassay for the qualitative, presumptive detection of THC Metabolites (11-nor-Δ^9-THC-9-carboxylic acid) in human urine. When marijuana is ingested, the drug is metabolised by the liver. The primary urinary metabolite of marijuana is 11-nor-Δ^9-THC-9-carboxylic acid and its glucuronide. The designed cut-off concentration and direct calibrator is as follows:

Parameter	Calibrator	Cut-off (ng/ml)
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50

The HOMEMED Marijuana (THC) Urine Cassette Test is used to obtain a visual qualitative test result and is intended to assist in the determination of drug compliance.
This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PRINCIPLE

The HOMEMED Marijuana (THC) Urine Cassette Test is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.
During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible coloured line will appear in the test line region of the drug strip. The presence of a drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no coloured line will form in the test line region. A drug-positive urine specimen will not generate a coloured line in the test line region of the strip 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 coloured line will always appear at the control line region, indicating that the correct volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS

Materials provided	Materials not provided
25 Marijuana (THC) Urine Cassettes	Specimen collection container
25 Disposable pipettes	Timer
1 Package insert	

PRECAUTIONS

For *in vitro* diagnostic use only.

- Do not use after the expiration date indicated on the package. Do not use the test if the 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 do not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled by observing usual safety precautions (e.g. 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 testing.
- Do not eat, drink or smoke in the area where 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 standard procedures for the 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.
- Used testing materials should be discarded in accordance with local 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.
- Kits should be kept out of direct sunlight.
- The product is humidity-sensitive and should be used immediately after opened.
- Any test in an improperly sealed pouch should be discarded.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

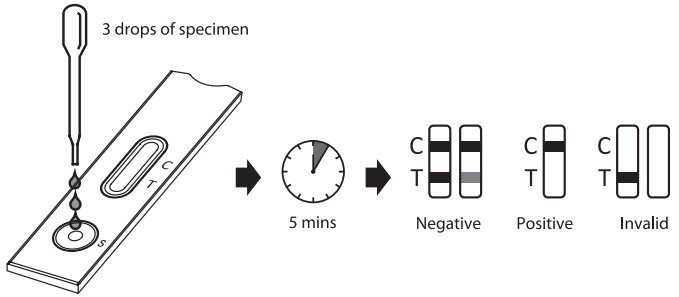
- The HOMEMED Marijuana (THC) Urine Cassette Test is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Urine specimens exhibiting visible precipitates should be centrifuged, filtered or allowed to settle to obtain a clear specimen for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods.
- Urine specimens may be stored at 2-8°C for up to 2 days. 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 of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

IMPORTANT: Test cassette, urine specimen and/or controls should be brought to room temperature (15-30°C) prior to testing. Do not open pouch until ready to perform the test.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean, flat surface. Label the test with patient or control identification.
3. Using the provided disposable pipette, transfer 3 drops of specimen (± 120 µl) to the specimen well (S) of the cassette and start the timer. *See illustration below.* NOTE: Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area.
4. The drug test result should be read at 5 minutes. Do not interpret the drug test result after 10 minutes.



INTERPRETATION OF RESULTS

(Refer to the illustration above)
Positive: Only one coloured line appears, in the control line region (C). No coloured line appears in the test line region (T). A positive test result indicates that the drug concentration exceeds the detectable level.
Negative: Two coloured lines appear. One line appears in the control line region (C) and another line appears in the test line region (T). A negative test result indicates that the drug is absent or the drug concentration is below the detectable level.
Invalid: Control line fails to appear. Results from any test which has not produced a control line at the specified read 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:

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

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control line region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 OF THE TEST

- The HOMEMED Marijuana (THC) Urine Cassette Test is for in vitro diagnostic use, and should only be used for the qualitative detection of drugs of abuse.
- This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) has

been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

- There is a possibility that technical or procedural error, as well as other substances or factors not listed may interfere with the test and cause incorrect results.
- Adulterants, such as bleach and/or alum in urine specimens, may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
- A positive test result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
- A negative test result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
- This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy: Accuracy of the HOMEMED Marijuana (THC) Urine Cassette Test was established by comparing a urine sample against GC/MS specification. The following results were tabulated:

% Agreement with GC/MS

Specimen	THC 50
Positive	96.8%
Negative	98.3%
Total	97.5%

Analytical Sensitivity: The sensitivity of the HOMEMED Marijuana (THC) Urine Cassette Test was determined by adding GC/MS confirmed controls to the urine sample at negative, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off and 3 times of cut-off concentrations. The results are summarized below:

Drug Concentration (Cut-off range)	n	THC 50	
		-	+
Negative	50	50	0
50% Cut-off	50	50	0
75% Cut-off	50	50	0
Cut-off	50	17	33
125% Cut-off	50	0	50
150% Cut-off	50	0	50
3x Cut-off	50	0	50

Analytical Specificity: The specificity of the HOMEMED Marijuana (THC) Urine Cassette Test has been tested by adding various drugs, drug metabolites and other compounds that are likely to be present in drug-free normal human urine. The HOMEMED Marijuana (THC) Urine Cassette Test performance at cut-off point is not affected when the pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at 1.005 to 1.03. The following compounds were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed below.

Marijuana parent 50 related compounds			
11-nor-Δ^9-THC-9-COOH	50	Δ^9-Tetrahydrocannabinol	15,000
11-nor-Δ^8-THC-9-COOH	50	Cannabinol	20,000
11-hydroxy-Δ^9-Tetrahydrocannabinol	50	Cannabidiol	>100,000
Δ^8-Tetrahydrocannabinol	15,000		

Non Cross-Reacting Compounds
The following compounds were found not to cross-react when tested at concentrations of 100 µg/ml:

Acetaminophen	Dextrorphan tartrate	(+)-Naproxen
Acetone	Dopamine	Oxalic Acid
Albumin	(-)-Ephedrine	Penicillin-G
Amitriptyline	(+/-)-Ephedrine	Pheniramine
Ampicillin	Erythromycin	Phenothiazine
Aspartame	Ethanol	Procaine
Aspirin	Furosemide	Protonix
Benzocaine	Glucose	Pseudoephedrine
Bilirubin	Guaiacol Glycerol Ether	Quinidine
b-Phenylethyl-amine	Hemoglobin	Ranitidine
Caffeine	Ibuprofen	Sertraline
Chloroquine	Imipramine	Tyramine
Chlorpheniramine	(+/-)-Isoproterenol	Trimeprazine
Creatine	Lidocaine	Venlafaxine
Dextromethorphan	Methadone	Vitamin C (Ascorbic Acid)
4-Dimethyllaminoantiyrine		

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

Σ 25	Catalog number	2°C 30°C	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Do not reuse

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