Marijuana (THC)
Dipstick
008W083 / 008W083-25

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

INTENDED USE

The ***Drug*Control THC Test** is a rapid chromatographic immunoassay for the detection of Marijuana metabolite (THC) in human urine at the cut-off concentration of 50ng/ml. The following table lists compounds that are positively detected in urine by the ***Drug*Control THC Test** at 5 minutes

TEST DEVICE	CALIBRATOR / related compounds	CUT-OFF LIMIT VALUE [ng / ml]
THC 50	**11-nor-Δ9-THC-9 COOH**	**50**
	11-nor-Δ8-THC-9 COOH	30
	Δ9-THC	17,000
	Δ8-THC	17,000
	Cannabinol	35,000

This assay provides only a qualitative, preliminary, analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (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 (Δ9-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-Δ9-tetrahydrocannabinol-9-carboxylic acid (Δ9-THC-COOH).

The ***Drug*Control THC Test** 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 ***Drug*Control THC Test** 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).

TEST PRINCIPLE

The ***Drug*Control THC Test** 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 strip. 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 device should remain in the sealed pouch until use.
- Do not use the test if the foil pouch is damaged
- Do not moisten nitrocellulose membrane with urine samples.
- Read the entire procedure carefully prior testing.
- 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.
- Humidity and temperature can adversely affect results.
- The used test device should be discarded according to federal state and local regulations.
- Do not reuse tests
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. Tests should be kept out of direct sunlight.
NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only. When removing test strips from canister, recap afterwards immediately.

- 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 testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

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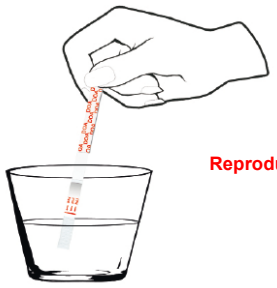
MATERIALS PROVIDED
- Test dipstick in pouch or canister
- Package insert

MATERIALS REQUIRED, BUT NOT PROVIDED
- Specimen collection container
- Timer
- Positive and negative controls



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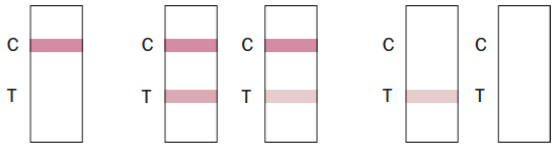
DIRECTIONS FOR USE
1. **Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.**
2. Bring the pouch / canister to room temperature before opening it
3. Remove the Test Dipstick from the sealed pouch or canister and use it within one hour.
4. With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds. **Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip.**
5. Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear.
6. Read results at 5 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS



Positive **Negative** **Invalid**

Positive: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the THC concentration is above the detectable cut-off level. (substances & cut-off concentrations see table on page 1).

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 THC concentration is below the detectable cut-off level.

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 Dipstick. If the problem persists, discontinue using the Test Dipstick immediately and contact your local distributor.

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

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 Dipstick; 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
- The ***Drug*Control THC Test** 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[2,3].
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- This test does not distinguish between drugs of abuse and certain medications.
- The ***Drug*Control THC Test** is intended for use with human urine specimens only.

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 ***Drug*Control THC Test** has a sensitivity of 50ng/ml.

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PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the *DrugControl* THC **Test** 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:

THC		*Other THC Rapid Test*		*Total Results*
		Positive	*Negative*	
DrugControl THC Test	*Positive*	*41*	*0*	*41*
	Negative	*0*	*59*	*59*
Total Results		*41*	*59*	*100*
% Agreement with this Test		***>99.9%***	***>99.9%***	***>99.9%***

A side-by-side comparison was conducted using the *DrugControl* **THC Test** 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:

THC		*GC/MS*		*Total Results*
		Positive	*Negative*	
DrugControl THC Test	*Positive*	*92*	*3*	*95*
	Negative	*2*	*153*	*155*
Total Results		*94*	*156*	*250*
% Agreement with this Test		***97.9%***	***98.1%***	***98.0%***

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor-Δ9-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:

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	*-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*

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:

THC 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 *DrugControl* **THC Test** 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 75 ng/mL. The spiked, pH-adjusted urine was tested with the *DrugControl* **THC Test** in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

DrugControl®

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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 ***Drug*Control THC Test** at a concentration of 100µg/ml

Non Cross-Reacting Compounds

4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
L-Ascorbic acid
D,L-Amphetamine
L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
(±)-Brompheniramine
Caffeine
Cannabidiol
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
(-)-ψ-Ephedrine
Erythromycin
b-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
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
Methoxyphenamine
(+) 3,4-Methylenedioxy-amphetamine
(+) 3,4-Methylenedioxy-methamphetamine
Methylphenidate
Methyprylon
Morphine-3-b-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
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
b-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3-Acetate
Tetrahydrocortisone 3 (b-D-glucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D, L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tryptophan
Tyramine
D, L-Tyrosine
Uric acid
Verapamil
Zomepirac

LIMITATIONS

It is impossible to check any and all - other than those drugs mentioned in the product insert - for cross-reactivity or any other influences to the to be detected drug of abuse (DOA).
If the patient takes a „cocktail“ of several different drugs or medication cannot be excluded that a non-reproducible cross-reaction can falsified the test result.

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

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Expiration date
	Read instructions for use		Store at
	Keep away from direct sunlight	REF	Ordering number
	Keep dry		

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

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