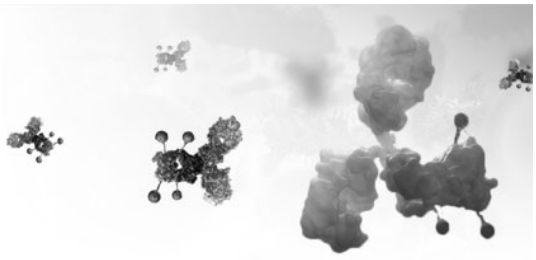

Tetrahydrocannabinol Rapid Test (DTS175)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Intended Use

Rapid THC Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of THC and its metabolites in human urine specimens. The presence of 11-nor-Δ9-THC-9-COOH in human urine above a cut-off level of 50 ng/ml can be detected. This assay may be used in the point of care setting.
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) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

General Description

The agents of Marijuana that cause various biological effects in humans are called cannabinoid. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoid could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. Δ9-THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor-Δ9-THC-9-COOH, which are found within hours of exposure and remain detectable in the urine for 3-10 days after smoking. However, the length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

Principles of Testing

Rapid THC Test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between drug conjugate and free drug which may be present in the urine specimen being tested. When drug is present in the urine

45-1 Ramsey Road, Shirley, NY 11967, USA
Email:info@creative-diagnostics.com
Tel: 1-631-624-4882 Fax: 1-631-938-8221

specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, 50 ng/ml, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Reagents And Materials Provided

1. Instructions for use.
2. Rapid THC Test device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
3. Test zone: contains THC bovine protein antigen conjugates.
4. Control zone: contains Goat anti-mouse IgG antibody.
5. Conjugate pad: contains mice monoclonal anti-THC antibody.

Materials Required But Not Supplied

1. Urine collection container
2. Timer or clock

Storage

The test device should be stored at 2 to 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

Specimen Collection And Preparation

It is required that approximately 150 µl of sample for each test. Fresh urine specimens do not need any special handling or treatment. Specimens should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8°C or frozen up to 7 days. Specimens should be thawed and brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

Assay Procedure

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Dip the strip into the urine specimen with the arrow pointing toward the sample. The sample level should not be higher

than the arrow pointed maximum line.

4. Hold the strip in the urine until a reddish color appears at the test area (approximately 20 seconds).
5. Withdraw the strip and place it face up on a clean, non-absorptive surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line.
6. Read the results at 5 minutes after adding the sample.
7. Do not interpret the result after 5 minutes.

Quality Control

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

The Rapid Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Interpretation Of Results	**Negative:** Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result indicates that the THC concentration in the specimen is either zero or less than cut-off level. **Positive:** One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the THC level in the specimen is above the cut-off level. **Invalid:** If there is no colored band in control line zone, the test result is invalid. Retest the sample with a new device. **Note:** A borderline (+/-) in test line zone should be considered negative result.
Reference Values	Rapid THC Test is a qualitative assay. It identifies 11-nor-Δ9-THC-9-COOH in human urine at a concentration of 50 ng/ml or higher. The concentration of the THC cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.
Precision	The accuracy of Rapid THC Test was evaluated in comparison to GC/MS at a cut-off of 50 ng/ml of 11-nor-Δ9-THC-9-COOH. Eighty eight urine specimens with GC/MS confirmed 11-nor-Δ9-THC-9-COOH concentration were evaluated in this study. The results are summarized and presented below: Positive % agreement: 84.1; Negative % agreement: 98.2.

Two specimens were found discrepant between the RapidTHC and GC/MS method. When compared those data, 50% (1 out of 2) of the discrepancy specimens were found between -25% and +25% cut-off concentration (37.5 - 62.5 ng/ml).

	(-)		(+)		
Rapid THC Test	GC/MS Negative (less than -25% cut-off)	Near cutoff negative (between –25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	Percent agreement with GC/MS
Positive	1	1	3	35	95
Negative	44	4	0	0	100
Total	45	5	3	35	N = 88

Sensitivity

The cut-off concentration (sensitivity level) of Rapid THC Test is determined to be 50ng/ml.

Specificity

The specificity for Rapid THC Test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The Rapid THC Test performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed not to interfere with RapidTHC test at the listed concentrations.

Glucose: 2000 mg/dl; Human albumin: 2000 mg/dl; Human hemoglobin: 10 mg/dl; Urea: 4000 mg/dl; Uric acid: 10 mg/dl.

2. Specificity

The following table lists compounds that are detected by Rapid THC Test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Each listed substance that commonly found in the urine was evaluated and indicated negative result at concentration of 100 µg/ml.

Acetaminophen, 4-Acetamidophenol, Acetylsalicylic acid, Amikacin, Amitriptyline, Amphetamine, Amobarbital, Arterenol, Aspartame, Ascorbic acid, Atrophine, Caffeine, Camphor, Chloroquine, Chlopheniramine, Cortisone, Deoxyephedrine, Dextromethorphan, Digitoxin, Digoxin, Diphenhydramine, Ecgonine, Ecgonine methyl ester, Ephedrine, Epinephrine, Gentisic, Guaiacol glycer ester, Histamine, Hydrochlorothiazide, Homatrophine, Imipramine, Ibuprofen, Isoproterenol, Ketamine, Lidocaine, Meperidine, Methadone, Methamphetamine, 3,4±MDMA, Methaqualone, Methylphenid, Neomycin, Niacinamide, Oxazepam, Perphenazine, Penicillin G, Phenylethylamine-α, Phenylpropanolamine, Promethazine, Pseudoephedrine, Quinine antidine, Salicylic acid, Tetracycline, Tetrahydrozoline, Theophyline, Thioridazine, Trifluoperazine, Tryptophan, Tyramine.

45-1 Ramsey Road, Shirley, NY 11967, USA
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Compounds	*Con. (ng/ml)*
11-nor-Δ9-THC-9-COOH	50
11-nor-Δ8-THC-9-COOH	37.5
11-Hydroxy- Δ 9-THC	5000
Δ8-Tetrahydrocannabinol	15000
Δ9-Tetrahydrocannabinol	25000

Reproducibility

The precision study was performed by three individuals observing the test result to determine the random error of visual interpretation. The test results were found to have no significant differences between the three observers.

Device	Control Con. ng/ml	No. of Tested	No. of positive			No. of borderline #			No. of negative		
			1*	2*	3*	1*	2*	3*	1*	2*	3*
THC	25	40							40	40	40
	37.5	40				1	1	1	39	39	39
	50	40	39	39	39	1	1	1			
	62.5	40	40	40	40						
	75	40	40	40	40						

Precautions

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

Limitations

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance.

If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

References

1. Urine testing for drugs of abuse, NIDA Research Monograph 73 (1986)
2. Steven B. Karch, Drugs of abuse hand book, CRC Press, 1st. Ed. (1998)
3. Ray H. Liu and Bruce A. Goldberger, Handbook of workplace drug testing, AACC Press, Washington DC (1995)

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