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IVD



See external label



2°C-30°C



Σ=25 or 50 tests

REF

Cat. #121028-1

OneStep Marijuana Urine RapiDip™ InstaTest

FOR THE QUALITATIVE ASSESSMENT OF CANNABINOID (THC)
IN HUMAN URINE

For in vitro Diagnostic and Forensic Use

INTENDED USE

Cortez Diagnostics, Inc. THC RapiDip™ is an immunochromatography based one step in vitro test. It is designed for qualitative determination of THC in human urine specimens. This assay has not been evaluated in the point of care location and is for use by Healthcare Professionals only

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.

SUMMARY AND EXPLANATION

THC. 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. Δ^9 -THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor- Δ^9 -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.

PRINCIPLE

Cortez Diagnostics, Inc. THC RapiDip™ is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine 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, 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.

MATERIAL PROVIDED

1. Cortez Diagnostics, Inc. THC RapiDip™ 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.
 - Test zone: contains THC bovine protein antigen conjugates
 - Control zone: contains Goat anti-mouse IgG antibody
 - Conjugate pad: contains mice monoclonal anti-THC antibody.
2. Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

STORAGE AND STABILITY

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.

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.

SPECIMEN COLLECTION AND PREPARATION

It is required that approximately 150µl of sample for each test. Fresh urine does not require any special handling or pretreatment. Specimen 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 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.

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 Cortez Diagnostics, Inc. THC RapiDip™ 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.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from 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 20seconds).
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.
Do not interpret the result after 5 minutes.

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 result for that particular test(s). The negative result does not indicate the absence of THC in the specimen, it only indicates the level of tested drug in the specimen is 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 the level of THC in the specimen is above the cut-off level.

Invalid:

If there are 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.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with THC RapiDip™ indicates only the presence of THC 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.

EXPECTED RESULTS

The THC RapiDip™ is a qualitative assay. It identifies 11-nor- Δ^9 -THC-9-COOH in human urine at a concentration of 50ng/ml or higher. The concentration of the THC can not 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.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Cortez Diagnostics, Inc. THC test was evaluated in comparison to GC/MS at a cut-off of 50 ng/ml of 11-nor- Δ^9 -THC-9-COOH. One hundred and fourteen urine specimens with GC/MS confirmed 11-nor- Δ^9 -THC-9-COOH concentration were evaluated in this study. The results are summarized and presented below:

THC Test	(-)		(+))		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	4	3	7	30	84.1
Negative	50	5	1	0	98.2
Total	54	8	8	30	

Positive % agreement: 84.1, Negative % agreement: 98.2

Eight specimens were found discrepant between the Cortez Diagnostics, Inc. THC and GC/MS method. When compared those data, 50% (4 out of 8) of the discrepancy specimens were found between -25% and +25% cut-off concentration (37.5 – 62.5 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of THC RapiDip™ has been determined to be: THC 50 ng/ml.

C. Precision

The precision of THC RapiDip™ was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 50% above and 50% below cut-off specimens are 100% agreed by three observers:

Device	Control Con (ng/ml)	Number 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						

D. Specificity

The specificity for THC RapiDip™ 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 THC RapiDip™ 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 did not interfere with THC RapiDip™ 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 THC RapiDip™ which produced positive results when tested at levels equal or greater than the concentrations listed below:

Test	Compounds	Cut-off (ng/ml)
THC	11-nor- Δ^9 -THC-9-COOH	50
	11-nor- Δ^8 -THC-9-COOH	37.5
	11-hydroxy- Δ^9 -THC	5000
	Δ^8 -Tetrahydrocannabinol	15000
	Δ^9 -Tetrahydrocannabinol	25000

The following compounds show no cross-reactivity at concentration up to 100 µg/ml (by adding in negative urine):

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin	Amitriptyline
Amphetamine	Amobarbital	Arterenol	Aspartame	Ascorbic acid
Atrophine	Caffeine	Camphor	Chloroquine	Cocaine
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	Methaqualon	
Methylphenid	Neomycin	Niacinamide	Oxazepam	Perphenazine
Penicillin G	Phenylethylamine-α	Phenylpropanolamine	Promethazine	
Pseudoephedrine	Quinine antidine	Salicylic acid	Tetracycline	
Tetrahydrozoline	Theophyline	Thioridazine	Trifluoperazine	Tryptophan
Tyramine				

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