Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep Marijuana (THC) Urine RapiCard™ InstaTest

REF 121027-1-44

IVD See external Label 2-30°C ∑=1 Test

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

INTENDED USE

The Cortez THC RapiCard™ (Urine) InstaTest 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.

This assay provides only a 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 AND EXPLANATION

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 (Δ 9-THC-9-COOH).

The Cortez THC RapiCard™ (Urine) InstaTest 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 Cortez THC RapiCard™ yields a positive result when the concentration of Marijuana in urine exceeds 50 ng/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 Cortez THC RapiCard™ (Urine) InstaTest 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 cassette. The antibody coated particles will then be captures 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.

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 a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

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.

MATERIALS

Materials provided

- THC Test RapiCard™
- Dropper
- Product Insert

Materials required but not provided

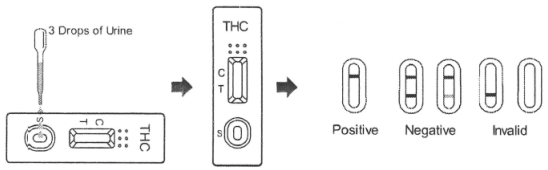
- Specimen collection container
- Timer

ASSAY PROCEDURE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the THC RapiCard™ from the sealed pouch and use it within one hour.

2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 120µl) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below:



3. Wait for the color line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

RESULTS

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Marijuana concentration is below the detectable level of 50 ng/ml.
***NOTE:** The shade of color in the test line region (T) may vary depending on the concentration of 11-nor-Δ9-THC-9-COOH (THC metabolite) present in the specimen. Therefore, any shade of color in the test line region (T) should be considered negative.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Marijuana concentration exceeds the detectable level of 50 ng/ml.
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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the Cortez Marijuana (THC) RapiCard™ 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:

Method		Other THC Rapid Test		Total Results
THC RapiCard™	Results	Positive	Negative	
	Positive	41	0	41
	Negative	0	59	59
Total Results		41	59	100
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using the Cortez Marijuana (THC) RapiCard™ and GC/MS at the cut-off of 50 ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
THC RapiCard™	Results	Positive	Negative	
	Positive	92	3	95
	Negative	2	153	155
Total Results		94	156	250
% Agreement		97.9%	98.1%	98.0%

Analytical Sensitivity

A drug-free urine pool was spiked with 11-nor-Δ9-THC-9-COOH at the following concentrations: 0 ng/ml, 25 ng/ml, 37.5 ng/ml, 50 ng/ml, 75 ng/ml, and 150 ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

11-nor-Δ9-THC-9-COOH 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

Analytical Specificity

The following table lists compounds and their respective concentrations in urine that yield a positive result in the Cortez THC (Urine) RapiCard™ at 5 minutes.

Compound	Concentration(ng/mL)
Cannabinol	35,000
11-nor-Δ8-THC-9-COOH	30
11-nor-Δ9-THC-9-COOH	50
Δ8-THC	17,000
Δ9–THC	17,000

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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-THC-9-COOH, 25% 11-nor-Δ9-THC-9-COOH, above and below the cut-off, and 50% 11-nor-Δ9-THC-9-COOH above and below the 50 ng/ml cut-off was provided to each site. The following results were tabulated:

11-nor-Δ9-THC-9-COOH 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 25 ng/mL and 75 ng/mL of 11-nor-Δ9-THC-9-COOH. The Cortez THC RapiCard™ (Urine) 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-THC-9-COOH to 25 ng/mL and 75 ng/mL. The spiked, pH-adjusted urine was tested with The Cortez THC RapiCard™ (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

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 Cortez THC RapiCard™ (Urine) at a concentration of 100 µg/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
Bnezphetamine
Bilirubin
(±)-Brompheniramine
Caffeine
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenae
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
(-)-ψ-Ephedrine
Erythromycin
β-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
(+)3,4-Methylenedioxy-amphetamine
(+)3,4-Methylenedioxy-methamphetamine
Methylphenidate
Methylprylon
Morphine-3-β-D-glucoronide
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
Pnetazocine
Pentobarbital
Perphenazine
Phencyclidine
Prednisolone
Prednisone
Procaine
Promazine
Promethzine
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 (β-D-glucoronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D,L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Levorphanol
Loperamide
Mparotiline
Meprobamate
Methadone
Methoxyphenamine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
D,L-Tryptophan
Tyramine
D,L-Tyrosine
Uric acid
Verapimil
Zomepirac

STORAGE

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this test cassette; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

LIMITATION OF PROCEDURE

1. The Cortez THC RapiCard™ (Urine) InstaTest provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (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.

EXPECTED VALUES

This negative result indicates that the Marijuana concentration is below the detectable level of 50 ng/ml. Positive result means the concentration of THC is above the level of 50 ng/ml. The Cortez THC RapiCard™ has a sensitivity of 50 ng/ml

PRECAUTION

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

REFERENCE

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.

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