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IVD	See external label	Σ=25 tests	2°C-30°C	REF Cat # 121035-1

OneStep

Methamphetamine

RapiCard™ InstaTest

Cat # 121035-1

FOR THE QUALITATIVE ASSESSMENT OF METHAMPHETAMINE
AND ECSTASY IN HUMAN URINE

For in vitro Diagnostic and Forensic Use

INTENDED USE

The Cortez Diagnostics, Inc. OneStep MET RapiCard™ InstaTest is an immunochromatography based one step in vitro test. It is designed for qualitative determination of Methamphetamine in human urine specimens above a cut-off level of 1000 ng/ml. 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.

SUMMARY AND EXPLANATION

Methamphetamine is the most popular systhetic derivative of the amphetamines. It is a potent sympathomimetic agent with therapeutic applications. Acute large doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. More acute response produces anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in the urine as amphetamine and oxized and deaminated derivatives. However, 10-40% of methamphetamine is excreted unchanged. Methamphetamine is generally detectable in the urine for 3 to 5 days after use.
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.

TEST PRINCIPLE

The Cortez OneStep MET RapiCard™ InstaTest 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 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, 1000 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.

MATERIALS PROVIDED

1. Instructions for use.
2. Cortez MET 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.
   Test zone: contains Methamphetamine bovine protein antigen conjugates
   Control zone: contains Goat anti-mouse IgG antibody
   Conjugate pad: contains mice monoclonal anti-methamphetamine antibody

MATERIALS 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^{o} 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 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^{o}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.

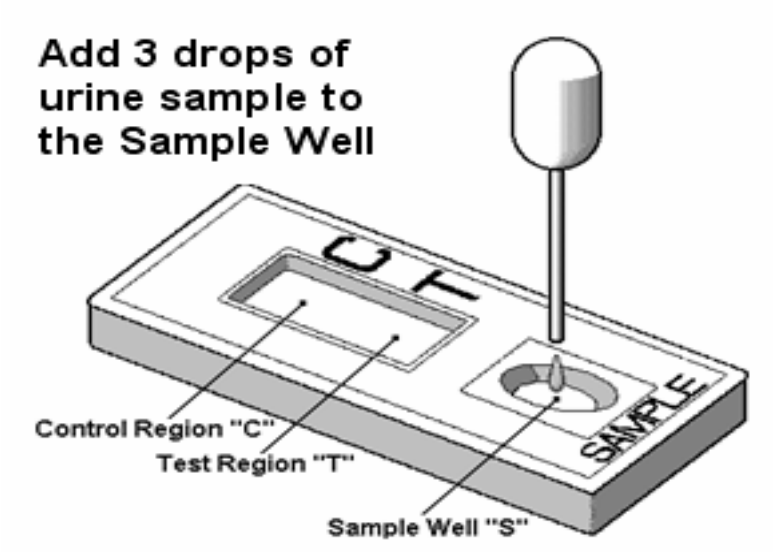
QUALITY CONTROL

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 is not provided with this test kit are commercially available.

The Cortez 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.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 µl) of sample in to the sample well.
5. Read the results at 5 minutes after adding the sample.
   Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

Negative:

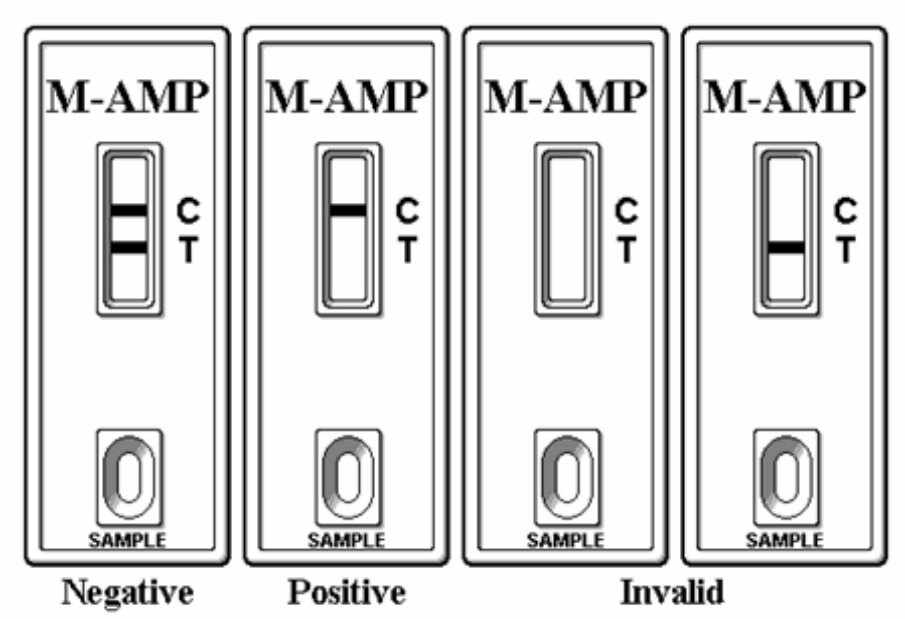
Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result indicates that the Methamphetamine concentration in the specimen is either zero or less than cut-off level.

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 Methamphetamine level 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 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 to the "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 Cortez Diagnostics, Inc. OneStep MET RapiCard™ InstaTest is a qualitative assay. It identifies methamphetamine in human urine at a concentration of 1000 ng/ml or higher. The concentration of the methamphetamine 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.

PERRFOMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Cortez MET test was evaluated in comparison to GC/MS at a cut-off of 1000 ng/ml of (+) methamphetamine. Ninety nine urine specimens with GC/MS confirmed (+) methamaphetamine concentration were evaluated in this study. The results are summarized and presented below:

	(-)		(+)		
Cortez MET 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	0	0	4	41	100.0
Negative	44	6	4	0	92.6
Total	44	6	8	41	

Positive % agreement: 100, Negative % agreement: 92.6
Four specimens were found discrepant between the Cortez MET and GC/MS method. When compared those data, 100% (4 out of 4) of the discrepancy specimens were found between –25% and +25% cut-off concentration (750 – 1250 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of Cortez MET test is determined to be 1000ng/ml.

C. Precision

The precision study was performed by three individuals observing the test result to determine the random error of visual interpretation. The test result 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***
MET	500	40							40	40	40
	750	40							40	40	40
	1000	40	24	20	20	61	20	20			
	1250	40	37	35	37	3	5	3			
	1500	40	40	40	40						

D. Specificity

The specificity for Cortez MET testy 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 Cortez OneStep MET RapiCard™ InstaTest 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 Cortez MET 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 Cortez MET test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Concentration. (ng/ml)
(+)Methamphetamine	1000
(±)3, 4Methylenedioxymethamphetamine	1000
(Ecstasy)	>100 µg/ml
D-Amphetamine	>100 µg/ml
L-Amphetamine	>100 µg/ml
(±)3, 4Methylenedioxyamphetamine	>100 µg/ml
Chloroquine	>100 µg/ml
(-) Ephedrine	>100 µg/ml
-Phenylethylamine	>100 µg/ml
Procaine	>100 µg/ml
d-Pseudoephedrine	>100 µg/ml
Rantidine	

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

Acetaminophen 4-Acetamidophenol Acetylsalicylic acid
Amikacin Acetaminophen 4-Acetamidophenol Acetylsalicylic acid
Amikacin Amitriptyline Arterenol
Aspartame D,l-Amphetamine Ascorbic acid
Atrophine Caffeine Camphor
Chloroquine Chlopheniramine Cortisone
Deoxyephedrin 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 Methaqualone Methylphenidate
Morphine Neomycin Niacinamide
Perphenazine Penicillin G Phenylethylamine-α
Phenylpropanolamine Promethazine Pseudoephedrine
uinine antidine Salicylic acid Tetracycline
Tetrahydrozoline Theophyline
11-nor-Δ^8–THC-9-COOH (10 µg/ml)
11-nor-Δ^8–THC-9-COOH (10 µg/ml)
Thioridazine Trifluoperazine Tryptophan
Tyramine

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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2005-01-14	DA-Methamphetamine-2009

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