Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep MDMA (Ecstacy) RapiDip™ InstaTest

REF 121033-1-21

IVD See external Label 2°C 30°C Σ 25 Tests

Sensitivity	500 ng/ml

INTENDED USE

The Cortez Diagnostics, Inc. OneStep MDMA RapiDip™ InstaTest is an immunochromatography based one step in vitro test.

SUMMARY AND EXPLANATION

MDMA, most commonly known today by the street name ecstasy (offen abbreviated to E, X, or XTC), is a semisynthetic entactogen of the phenethylamine family. The primary effects of MDMA include feelings of openness, euphoria, empathy, love, and heightened self-awareness, the short-term health risks of taking MDMA include hypertension, dehydration and hyperthermia, the effects of long-term use in humans are debatable and the subject of much controversy, particularly with regard to the risks of severe long-term depression as a result of a reduction in the natural production of serotonin. Ecstasy affects the regulation of the body's internal system, the use of ecstasy can be very dangerous when combined with other drugs.

TEST PRINCIPLE

The Cortez Diagnostics, Inc. OneStep MDMA RapiDip™ 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 500 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.

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.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Instructions for use.
2. Cortez MDMA 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 MDMA bovine protein antigen conjugates.
4. Control zone: contains Goat anti-mouse IgG antibody.
5. Conjugate pad: contains mice monoclonal anti-MDMA antibody.

Materials required but not provided

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

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. ***Do not interpret the result after 10 minutes.***

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 MDMA (Ecstacy) 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 MDMA(Ecstacy) level in the specimen is above the cut-off level.
- **Invalid:** If there are no colored bands in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A b*orderline (+/-) in test line zone be considered negative result.*

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Cortez MDMA test was evaluated in comparison to GC/MS at a cut-off of 500 ng/ml of MDMA. 110 urine specimens with GC/MS confirmed MDMA (Ecstacy) concentration were evaluated in this study. The results are summarized and presented below:

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	(-)		(+)		
Cortez MDMA 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	2	7	45	94.5
Negative	46	8	3	0	96.4
Total	46	10	10	45	N=110

Positive % agreement: 94.5, Negative % agreement: 96.4.
Four specimens were found discrepant between the Cortez mdmA and GC/MS method. When compared those data, 100% (5 out of 5) of the discrepancy specimens were found between –25% and +25% cut-off concentration (375 – 625 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of Cortez MDMA test is determined to be 500ng/ml of MDMA.

C. Precision

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 1*	2*	3*	No. of borderline 1*	2*	3*	No. of negative 1*	2*	3*
MDMA	0	42							42	42	42
	250	42							42	42	42
	375	42							42	42	42
	500	42	34	32	34	8	10	8			
	625	42	42	42	42						
	750	42	42	42	42						

D. Specificity

The specificity for Cortez MDMA 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 Diagnostics, Inc. OneStep MDMA RapiDip™ InstaTest performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.5 to 9.0 and 1.005 to 1.035.

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 MDMA test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Con. (ng/ml)
MDMA	500
(±) 3,4-MDA	500
(+) Methamphetamine	100,000

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
Amitriptyline	Amobarbital	Amphetamine
Aspartame	Ascorbic acid	Atrophine
Camphor	Chloroquine	Chlopheniramine
Deoxyephedrine	Dextromethorphan	Digitoxin
Diphenhydramine	Ecgonine	Ecgonine methyl ester
Epinephrine	Gentisic	Guaiacol glycer ester
Hydrochlorothiazide	Homatrophine	Imipramine
Isoproterenol	Ketamine	Lidocaine
Methadone	Methamphetamine	Metoprolol
Methylphenidate	Neomycin	Niacinamide
Perphenazine	Penicillin G	Phenylethylamine-α
Promethazine	Pseudoephedrine	Quinine antidine
Tetrahydrozoline	Theophyline	11-nor-Δ^8-THC-9-COOH(10 µg/ml)
11-nor-Δ^8-THC-9-COOH(10 µg/ml)	Thioridazine	Trifluoperazine
Tyramine	Perphenazine	Chlopromazine

Amikacin	Ibuprofen
Arterenol	Meperidine
Caffeine	Methaqualone
Cortisone	Oxazepam
Digoxin	Phenylpropanolamine
Ephedrine	Salicylic acid Tetracycline
Histamine	Tryptophan
	Clomipramine

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 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.

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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 "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 VALUES

The Cortez Diagnostics, Inc. OneStep MDMA RapiDip™ InstaTest is a qualitative assay. It identifies MDMA in human urine at a concentration of 500 ng/ml or higher. The concentration of the MDMA 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.

PRECAUTION

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

ISO 13485 ISO 9001 **Diagnostic Automation/ Cortez Diagnostics, Inc. 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA**	
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