Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Ketamine Urine RapiDip™ InstaTest

REF **120301-1**

IVD See external Label 2°C 30°C 1 Test

Specificity	**100%**
Sensitivity	**1000 ng/ml**

INTENDED USE

Ketamine test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of ketamine in human urine specimens at cut-off level of 1000 ng/ml. 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

Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and humen anaesthetic. Certain doses of ketamine can cause dream-like states and hallucinatioins. In high does, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolized in the liver and excreted through the kidney. The half-live of ketamine in the body is around three hours.

TEST PRINCIPLE

Ketamine 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 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.

SPECIMEN COLLECTION AND PREPARATION

It is required that approximately 120 - 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 2-8ºC 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. Ketamine 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-rabbit IgG antibody.
3. Test zone: contains ketamine protein antigen conjugates.
4. Control zone: contains Goat anti-rabbit IgG antibody.
5. Conjugate pad: contains mice monoclonal anti-ketamine 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 10 minutes minutes after adding the sample.

Test results may not be accurate 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 buprenorphine 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 buprenorphine 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. Sensitivity

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

B. Accuracy

The accuracy of the Rapid Ketamine Test was evaluated in ketamine spiked urine specimens. Forty (40) ketamine urine specimens were spiked with ketamine from 250 to 5000 ng/ml. 30 smples with ketamine concentration between 1500 and 5000 ng/nl were all found positive (100% agreement), 10 samples with Ketamine concentration between 250 and 750 ng/ml were found negative.

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			No. of borderline #			No. of negative		
			1*	2*	3*	1*	2*	3*	1*	2*	3*
	500	42							42	42	42
	750	42				1	1	2	41	41	40
KET	1000	42	32	30	32	10	12	10			
	1250	42	38	36	36	4	6	6			
	1500	42	42	42	42						

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D. Specificity

The specificity for Ketamine 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 Ketamine test performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 8.0 and 1.005 to 1.035.

The following substances were tested and confirmed not to interfere with Ketamine 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 Ketamine test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Concentration	Cross reactivity
Ketamine	1,000 ng/ml	100%
Norketamine	500 ng/ml	200%
Phencyclidine	25,000 ng/ml	4%
Tetrahyhydrozoline	50,000 ng/ml	2%
Chlopheniramine	100,000 ng/ml	1%
Dextromethorphan	100,000 ng/ml	1%
Lidocaine	100,000 ng/ml	1%
Promethazine	100,000 ng/ml	1%
d-Pseudoephedrine	100,000 ng/ml	1%
d-Amphetamine	100,000 ng/ml	1%

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

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid
Amitriptyline	Amobarbital	Arterenol
Ascorbic acid	Atrophine	Benzoyolecgonine
Camphor	Chloroquine	Cortisone
Digitoxin	Digoxin	Diphenhydramine
Ecgonine methyl ester	Ephedrine	Epinephrine
Guaiacol glycer ester	Histamine	Hydrochlorothiazide
Imipramine	Ibuprofen	Isoproterenol
Methylphenidate	Methamphetamine	Methadone
Morphine	Neomycin	Niacinamide
Oxycodone	Oxymorphone	Perphenazine
Phenylethylamine-α	Phenylpropanolamine	Quinine antidine

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 established 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.

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.

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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

Ketamine test is a qualitative assay. It identifies ketamine in human urine at a concentration of 100 ng/ml or higher. The concentration of the Ketamine 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.

STORAGE

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 product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

REFERENCES

1. Urine testing for drugs of abuse, NIDA Research Monograph 73 (1986)
2. InfoFacts-Club drugs, NIDA, May 2006. http://www.nida.nih.gov/infofacts/clubdrugs.html

ISO 13485
ISO 9001

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