Atlas Medical CE

One Step Ketamine Test Device(Urine)

A rapid, one step screen test for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine.

IVD *For in vitro diagnostic and professional use only*

Store at 2-30 °C

INTENDED USE & INTRODUCTION

The Ketamine Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of Ketamine in human urine specimens at the cut-off concentrations of 1,000 ng/ml using Ketamine as calibrator.

PRINCIPLE

The Ketamine Rapid Test Device detects Ketamine through visual interpretation of color development on the Device. Drug conjugates are immobilized on the test region of the membrane. During testing, the specimen reacts with antibodies conjugated to colored particles and precoated on the sample pad. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane.

If there are insufficient drug molecules in the specimen, the antibody-colored particle conjugate will bind to the drug conjugates, forming a colored band at the test region of the membrane. Therefore, a colored band appears in the test region when the urine is negative for the drug. If drug molecules are present in the urine above the cut-off concentration of the test, they compete with the immobilized drug conjugate on the test region for limited antibody binding sites. This will prevent attachment of the antibody-colored particle conjugate to the test region. Therefore, the absence of a colored band at the test region indicates a positive result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

- Test Device.
- Dropper.
- Package insert

Materials Required But Not Provided

- Specimen collection container
- Timer

PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- The test Device 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 Device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C). The test Device is stable through the expiration date printed on the sealed pouch.
- The test Device must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.

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 precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

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

PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test Device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

NEGATIVE:* Two lines adjacent to each drug name appear. One red line should be in the control region (C) of the specific drug test, and another apparent red or pink line adjacent to each drug test should be in the test region (T) of the specific drug test.

NOTE:

The shade of red in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One colored line appears in the control region (C) of the specific drug test. No line appears in the test region (T) of the specific drug test. The absence of a test line indicates a positive result for that drug.

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 using a new test Device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Ketamine Test Device is for professional in vitro diagnostic use, and should be only used for the qualitative detection of drugs of abuse.
2. This assay provides a preliminary analytical test result only. 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 National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude

the possibility of urine adulteration prior to testing.

5. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the Ketamine Rapid Test Device was compared and checked against commercially available tests with a threshold value at the same cut-off levels. Urine samples taken from volunteers claiming to be non-users were examined under both tests. The results were >99.9% in agreement.

Reproducibility

The reproducibility of the Ketamine Rapid Test Device was verified by blind tests performed at four different locations. Samples with drug/metabolite concentrations at 50% of the cut-off were all determined to be negative, while samples with drug/metabolite concentrations at 200% of the cut-off were all determined to be positive.

Precision

Test precision was determined by blind tests with control solutions. Controls with drug/metabolite concentrations at 50% of the cut-off yielded negative results, and controls with drug/metabolite concentrations at 150% of the cut-off yielded positive results.

Specificity

The following tables list the concentrations of compounds (ng/mL) above which the One Step Ketamine Test Device identified positive results at 5 minutes.

KET 1000	**ng/ml**
Ketamine	1,000
Norketamine	1,000
Dextromethorphan	500
Dextrorphan tartrate	500
D-Norpropoxyphene	31,250
EDDP	800
Meperidine	12,500
Mephentermine hemisulfate salt	15,625
Methadone	50,000
D-Methamphetamine	12,500
3,4-Methylenedioxyethylamphetamine (MDEA)	25,000
Nordoxepin hydrochloride	25,000
Phencyclidine	5,000
Promazine	8,000
Promethazine	25,000
Paramethoxymethamphetamine (PMMA)	20,000

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REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry