Atlas Medical

Ketamine KET Rapid Test Strip (Urine)

IVD *For in vitro diagnostic and professional use only.*

2 ~ 30°C Store at 2-30 °c CE

INTENDED USE

The KET Rapid Test Strip (Urine) is a rapid visual immunoassay for the qualitative, presumptive detection of Ketamine in human urine specimens at the cut-off concentrations listed below:

Parameter	Calibrator	Cut-off (ng/mL)
KET (Ketamine)	Ketamine	1,000

INTRODUCTION

Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anaesthetic since 1970. About 90 percent of the ketamine legally sold is intended for veterinary use. It can be injected or snorted, but is sometimes sprinkled on tobacco or marijuana and smoked. Ketamine is frequently used in combination with other drugs, such as ecstasy, heroin or cocaine. Ketamine is also known as "special K" or "vitamin K." Certain doses of Ketamine can cause dream-like states and hallucinations. In high dose, 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-life of Ketamine in the body is around three hours. The Drug Enforcement Administration reports that overt effects can last an hour but the drug can still affect the body for up to 24 hours.

PRINCIPLE

The KET Rapid Test Strip (Urine) detects Ketamine through visual interpretation of color development on the strip. 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.

REAGENTS

Each test consists of a reagent strip. The amount of each antigen and/or antibody coated on the strip is less than 0.001 mg for antigen conjugates and goat anti-rabbit IgG antibodies, and less than 0.0015 mg for antibody components. The control zone of each test contains goat anti-rabbit IgG antibody. The test zone of each test contains drug-bovine protein antigen conjugate, and the conjugate pad of each test contains monoclonal anti-drug antibody and rabbit antibody-colored particle complex

Materials

Materials provided

- Test strips.
- Package insert.

Materials needed but not provided

- Positive and negative controls.
- Timer.
- Centrifuge.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch or canister is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch or closed canister until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The KET Rapid Test Strip (Urine) is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

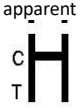
PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, or remove one strip from the canister, and use it as soon as possible. For best results, the assay should be performed within one hour. Canisters should be closed tightly after removing strips.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

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 OF THE TEST

1. The KET Rapid Test Strip (Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of Ketamine.
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 Ketamine only, and does not indicate or measure intoxication.
6. A negative result does not at any time rule out the presence of Ketamine in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between Ketamine and certain medications.

PERFORMANCE CHARACTERISTICS

A. **Accuracy** The accuracy of the KET Rapid Test Strip (Urine) 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.

B. **Reproducibility** The reproducibility of the KET Rapid Test Strip (Urine) was verified by blind tests performed at four different locations. Samples with Ketamine concentrations at 50% of the cut-off were all determined to be negative, while samples with Ketamine concentrations at 200% of the cut-off were all determined to be positive.

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

D. **Specificity** The following tables list the concentrations of compounds (ng/mL) above which the KET Rapid Test Strip (Urine) identified positive results at 5 minutes.

Ketamine related compounds	**Concentration (ng/ml)**
Ketamine	1,000
Norketamine	1,000
Dextromethorphan	500
Dextrorphan tartrate	500
D-Norpropoxyphene	31,250
Meperidine	12,500
Mephentermine hemisulfate salt	15,625
D-Methamphetamine	12,500
3,4-Methylenedioxyethylamphetamine (MDEA)	25,000
Nordoxepin hydrochloride	25,000
Phencyclidine	5,000
Promazine	8,000
Promethazine	25,000

The following compounds yielded negative results up to a concentration of 100 µg/mL:

Acetaminophen	Dicumarol	Metronidazole
Acetophenetidine	Diflunisal	MOR-3-Beta-D
Acetylcodeine	DL-Propanolol	Glucuronide
Acetylsalicylic acid	Digoxin	Nalorphine
Alprazolam	Dihydrocodeine	Naloxone
Amikacin	(+)-cis-Diltiazem	(+)-Naproxen
Aminopyrine	Dimenhydrinate	Nifedipine
Amitriptyline	4-Dimethylaminoantipyrin e	Nimesulide
Amoxicilline	Diphenhydramine	Nitrazepam
Amphetamine	DL-Tryptophan	Olanzapine
Ampicilline	DL-Tyrosine	Opipramol
Apomorphine	Dopamine	Oxalic acid
Aspartame Atropine	Doxylamine	Oxazepam
Baclofen	d-Propoxyphene	Oxymetazoline
Benzocaine	Ecgonine HCl	Pennicilline G
Bilirubin	Ecgonine methylester	Perphenazine
Bromazepam	Ephedrine	Pheniramine
Buprenorphine	(+/-)Epinephrine	Phenothiazine
Caffeine	Erythromycine	Phentermine
Cannabidiol	Estron 3 sulfate	(+/-)
Cannabinol	Ethylmorphine	Phenylpropanolam ine
Carbamazepine	Etodolac	beta-phenylethyla mine
Chloramphenicol	Fenfluramine	Prednisolone
Chlordiazepoxide	Fentanyl	Prednisone
Chloroquine	Flupentixol	Procaine
Chlorpheniramine	Fluoxetine	Prothipendyl
Chlorprothixene	Furosemide	Protriptyline
Cholesterol	Gastrozepin	Quetiapine
Chorptothixene	Gentamicin	Quinidine
Cimetidine	Gentisic acid	Ranitidine
Ciprofloxacin	Guaiacol Glyceryl Ether	Rifampicine
Citalopram	Hemoglobin	Risperidone
Clindamycin	Hydralazine	Salbutamol
Clobazam	Hydrochlorothiazide	Salicylic acid
Clomipramine	Hydrocodone	Secobarbital
Clonazepam	Hydrocortisone	Sertraline
Clonidine	Ibuprofen	Spironolactone
Clorazepate	Imipramine	Sulfamethoxazole
Clozapine	(-)Isoproterenol	Sulindac
Cocain	Ketoprofen	Temazepam
Codein	L - Thyroxine	Thebaine
(-)Cotinine	Lincomycin	Theophylline
Creatinine	Lidocaine	Thiamine
Cyclobenzaprine	Loperamide	Thioridazine
Delorazepam	L-Phenylephrine	Tobramycin
Diacetylmorphine	Maprotiline	Triamterene
Diazepam		Trimethoprim
Diclofenac	N-Methylephedrine	Trimipramine
	Metoclopramide	Desipramine HCl
	Metoprolol	Venlafaxine
		Verapamil
		Zolpidem
		EDDP

LITERATURE REFERENCES

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REF	Catalogue Number		Temperature limit
IVD	In Vitro diagnostic medical device		Caution
Σ	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