

KET

One Step Ketamine Test Strip (Urine)

*A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.
For professional in vitro diagnostic use only.*

INTENDED USE

The **One Step Ketamine Test Strip (Urine)** is a lateral flow chromatographic immunoassay for the detection of Ketamine in human urine.

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

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

Ketamine is a short-acting “dissociative” anesthetic due to its ability to separate perception from sensation. It also has hallucinogenic and painkilling qualities that seem to affect people in very different ways. Ketamine is chemically related to PCP ('Angel Dust'). Ketamine is occasionally administered to people but, more commonly, is used by vets for pet surgery. Generally street K is most often diverted in liquid form from vets' offices or medical suppliers. Ketamine generally takes 1-5 minutes to take effect. Snorted ketamine takes a little longer at 5-15 minutes. Depending on how much and how recently one has eaten, oral ketamine can take between 5 and 30 minutes to take effect. The primary effects of ketamine last approximately a 30-45 minutes if injected, 45-60 minutes when snorted, and 1-2 hours if used orally. The Drug Enforcement Administration reports that the drug can still affect the body for up to 24 hours.

The One Step Ketamine Test Strip (Urine) yields a positive result when the Ketamine in urine exceeds 1,000 ng/mL

PRINCIPLE

The One Step Ketamine Test Strip (Urine) is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Ketamine, if present in the urine specimen below 1,000 ng/mL, will not saturate the binding sites of the antibody coated particles in the test strip. The antibody coated particles will then be captured by immobilized Ketamine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Ketamine level exceeds 1,000 ng/mL because it will saturate all the binding sites of anti-Ketamine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test in the test strip contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

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

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip 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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

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

MATERIALS

Materials Provided

- Test strip
- Package insert

Materials Required but Not Provided

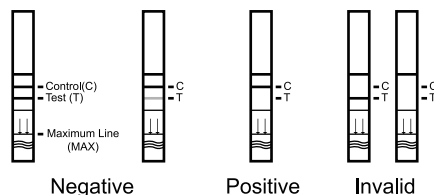
- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

- Remove the test strip from its foil wrapper or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the device with patient or control identifications.
- Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the urine over the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a minimum of 15 seconds in the urine and lay the strip flatly on a non-absorptive clean surface.
- Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: * **Two lines appear.** One red line should be in the control region (C), and another apparent red or pink line should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

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

POSITIVE: One red line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

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 strip. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The One Step Ketamine Test Strip (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.^{1,2}
- There is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

Ketamine (KET)

KET conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
1,500	40	40 positive	>99%
2,000	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at: 0 ng/mL, -50% cut-off; -25% cut-off; cut-off; +25% cut-off; +50% cut-off. Results were all positive at and above +25% cut-off and all negative at and below -25% cut-off for Ketamine. The data are summarized below:

KET Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	27	3
1,000	Cut-off	30	19	11
1,250	+25%	30	1	29
1,500	+50%	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The One Step Ketamine Test Strip (Urine) at a read time of 5 minutes.

Drug	Concentration (ng/ml)
KETAMINE (KET 1,000)	
Ketamine	1,000
Norketamine	3,000
Methoxy-amphetamine	12,500
Promethazine	25,000
4-hydroxyphenyl cyclohexyl piperidine	50,000

Effect of Urinary Specific Gravity

Twelve (12) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The One Step Ketamine Test Strip (Urine) was tested in duplicate using drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above cut-off levels. The spiked, pH-adjusted urine was tested with the One Step Ketamine Test Strip (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Interference Compounds

A study was conducted to determine the interference compounds of the test with compounds in either drug-free urine or Ketamine positive urine. The following compounds show no cross-reactivity when tested with the One Step Ketamine Test Strip (Urine) at a concentration of 100 µg/mL.

Non-interfering Compounds Tables

Acetophenetidin	Cortisone	Pseudoephedrine	Quinidine
N-Acetylprocainamide	Creatinine	Kynurenic Acid	Quinine
Acetylsalicylic acid	Dexamethasone	Labetalol	Salicylic acid
Amiloride	Dextromethorphan	Loperamide	Serotonin
Amoxicillin	Desipramine	Meprobamate	Sulfamethazine
Ampicillin	Diffunisal	Methoxyphenamine	Sulindac
l-Ascorbic acid	Digoxin	Methylphenidate	Tetracycline
Apomorphine	Droperidol	Nalidixic acid	Tetrahydrocortisone,
Aspartame	Ethyl-p-aminobenzoate	Naproxen	3-Acetate
Atropine	Ethopropazine	Niacinamide	Theobromine
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tolazamide
p-Aminobenzoic Acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
Beclomethasone	Furosemide	Octopamine	Thioridazine Hydrochloride
Caffeine	Gentisic acid	Oxalic acid	D/L-Tyrosine
Cannabidiol	Hemoglobin	Oxyphenbutazone	Tolbutamide
Carbamazepine	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Paclitaxel	Trimethoprim
Chlorpheniramine	α-Hydroxyhippuric acid	Perphenazine	D,L-Tryptophan
Chlorpromazine	Hydroxyprogesterone	Phenelzine	Uric acid
Cholesterol	Isoproterenol-(+/-)	Prednisone	Verapamil
Clonidine	Isoxsuprine	Prilocaine	Zomepirac

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