SCREEN®

SCREEN 1 KETAMINA (Urine) Package Insert

REF: SC-0067-25	English

A rapid test for the qualitative detection of Ketamine in human urine.
For medical and other professional in vitro diagnostic use only.

INTENDED USE

The KET Rapid Test Panel (Urine) is a rapid chromatographic immunoassay for the detection of Ketamine in human urine at a cut-off concentration of 1,000ng/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 dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use. Ketamine is excreted in the urine as unchanged drug (2.3%) and metabolites (96.8%).1
The KET Rapid Test Panel (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Ketamine in urine. The KET Rapid Test Panel (Urine) yields a positive result when Ketamine in urine exceeds 1,000ng/mL.

PRINCIPLE

The KET Rapid Test Panel (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 1,000ng/mL, will not saturate the binding sites of the antibody coated particles in the test. 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 1,000ng/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 because of drug competition, 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

The test contains mouse monoclonal anti-Ketamine antibody-coupled particles and Ketamine-protein conjugate. A goat antibody is employed in the control line system.

PRECAUTIONS

- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
- The test 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 should be discarded according to local regulations.

STORAGE AND STABILTY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

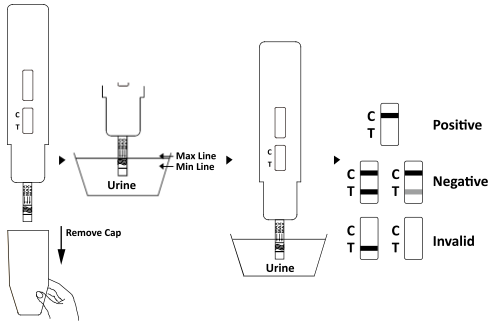
Urine Assay
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials Provided
• Test Panels • Package insert
Materials Required But Not Provided
• Specimen collection containers • Timer

DIRECTIONS FOR USE

Allow the test, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. **Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.**
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
NEGATIVE:* Two colored lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Ketamine concentration is below the detectable level (1,000ng/mL).
***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of ketamine present in the specimen. Therefore, any shade of color in the test line region (T) should be considered negative.
POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Ketamine concentration exceeds the detectable level (1,000ng/mL).
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. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line 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 practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The KET Rapid Test Panel (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]
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.
6. This test does not distinguish between drugs of abuse and certain medications.

EXPECTED VALUES

This negative result indicates that the Ketamine concentration is below the detectable level of 1000ng/ml. Positive result means the concentration of Ketamine is above the level of 1000ng/ml. The KET Rapid Test Panel has a sensitivity of 1000ng/ml.

PERFORMANCES CHARACTERISTICS

Accuracy
A side-by-side comparison was conducted using The KET Rapid Test Panel and a commercially available KET rapid test. Testing was performed on 105 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		Other KET Rapid Test		Total Results
KET Rapid Test Panel	Results	Positive	Negative	
	Positive	42	0	42
	Negative	0	63	63
Total Results		42	63	105
% Agreement		>99.9%	>99.9%	>99.9%

A side-by-side comparison was conducted using The KET Rapid Test Panel and GC/MS at the cut-off of 1,000ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
KET Rapid Test Panel	Results	Positive	Negative	
	Positive	77	3	80
	Negative	2	168	170
Total Results		79	171	250
% Agreement		97.5%	98.2%	98.0%

Analytical Sensitivity
A drug-free urine pool was spiked with Ketamine at the following concentrations: 0ng/mL, 500ng/mL, 750ng/mL, 1,000ng/mL, 1,250ng/mL, 1,500ng/mL and 3000ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Ketamine 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	26	4
1,000	Cut-off	30	16	14
1,250	+25%	30	4	26
1,500	+50%	30	0	30
3,000	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the KET Rapid Test Panel (Urine) at 5 minutes.

Compound	Conc. (ng/mL)	Compound	Conc. (ng/mL)
Ketamine	1,000	Tetrahydrozoline	500
Benzphetamine	25,000	d-Methamphetamine	50,000
(+) Chlorpheniramine	25,000	l-Methamphetamine	50,000
Clonidine	100,000	Methoxyphenamine	25,000
Dextromethorphan	2,000	(+)3,4-Methylendioxymethamphetamine (MDMA)	100,000
Disopyramide	25,000	d-Norpropoxyphene	25,000
EDDP	50,000	Pentazocine	25,000
Mephentermine	25,000	Phencyclidine	25,000
(1R, 2S) - (-)-Ephedrine	100,000	Promazine	25,000
4-Hydroxyphencyclidine	50,000	Promethazine	25,000
Levorphanol	50,000	Thioridazine	50,000
MDE	50,000	Meperidine	25,000

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Ketamine, 25% Ketamine above and below the cut-off, and 50% Ketamine above and below the 1000 ng/mL cut-off was provided to each site. The results are given below:

Ketamine Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
750	10	9	1	8	2	9	1
1250	10	1	9	1	9	2	8
1500	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 500ng/mL and 1,500ng/mL of Ketamine. The KET Rapid Test Panel (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 Ph unit increments and spiked with Ketamine to 500ng/mL and 1,500ng/mL. The spiked, pH-adjusted urine was tested with the KET Rapid Test Panel (Urine) in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity 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 KET Rapid Test Panel (Urine) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Dexamethasone	Ibuprofen	Phenolbarbital
Acetone	Diazepam	Imipramine	Phenothiazine
Acetophenetidine	Diclofenac	Indomethacin	Phentermine
N-Acetylprocainamide	Dicumarol	Insulin	trans-2-Phenyl-cyclopropylamine
Acetylsalicylic acid	Dicyclomine	Iproniazide	l-Phenylephrine
Albumine	Diflunisal	(-) Isoproterenol	β-Phenylethylamine
Albuterol	Digitoxin	Isoxsuprine	Phenylpropanolamine
Amantadine	Digoxin	Kanamycin	(d,l-Norephedrine)
Amikacin	(+) cis-Diltiazem	Ketoprofen	Prednisolone
Aminopyrine	Dimenhydrinate	Labetalol	Prednisone
Amitriptyline	4-Dimethylaminoantipyrine	Lidocaine	Probenecid
Amobarbital	5,5-Diphenylhydantoin	Lindance	5-β-Pregnane-3α,17α,21-triol-20-one
Amoxapine	Diphenhydramine	(Hexachlorocyclohexane)	Procaine
Amoxcilline	Doxylamine	Lithium cacbonate	Procyclidine
d,l-Amphetamine	Droperidol	Loperamide	d-Propoxyphene
Ampicilline	Ecgonine	Maprotiline	Protriptyline
Apomorphine	Ecgonine methylester	Meprobamate	d-Pseudoepherine
Ascorbic acid	Efavirenz (Sustiva)	Methaqualone	Quinacrine
Aspartame	EMDP	(±) 3,4-Methylendioxy-amphetamine (MDA)	Quinidine
Atenolol	Emetine dihydrochloride	Methylphenidate	Quinine
Atropine	hydrate	Methyprylon	R-(-) Deprenyl
Baclofen	(±) Epinephrine	Metoclopramide	Ranitidine
Benzilic acid	Erythromycine	Metoprolol	Riboflavin
Benzoic acid	β-Estradiol	Metronidazole	Salbutamol
Benzoylecgonine	Estrone 3 sulfate	Morphine-3-β-d glucuronide	Salicylic acid
Bilirubin	Ethanol (Ethyl alcohol)	Morphine sulfate	Secobarbital
Brompheniramine	Ethyl-p-aminobenzoate (Benzocaine)	Nalidixic acid	Sodium chloride
Buprenorphine	Etodolac	Nalorphine	Spironolactone
Buspirone	Fanprofazone	Naloxone	Sulfamethazine
Caffeine	Fenfluramine	Naltrexone	Sulfamethoxazole
Cannabidiol	Fenoprofen	α-Naphthaleneacetic acid	Sulfisoxazole
Cannabinol	Fentanyl	Naproxen	Sulindac
Carisoprodol	Fluoxetin	Niaciamide	Temazepam
Cephalexin hydrate	Furosemide	Nifedipine	Tetracyline
Chloral hydrate	Gentamicin	Nimesulide	Thebaine
Chloramphenicol	Gentisic acid	Norcodein	Theophylline
Chlordiazepoxide	d-(+) Glucose	Norethindrone	Thiamine
Chloroquine	Guaiacol glyceryl ether (Carbamate)	Norfluoxetine	Thiothixene
Chlorothiazide	Haloperidol	Normorphone	l-Thyroxine
Chlorpromazine	Hemoglobin	Noscapine	Tobramycin
Chlorpropamide	Hydralazine	d,l-Octopamine	Tolbutamide
Chlorprothixene	Hydrochlorothiazide	Orphenadrine	Trazodone
Cholesterol	Hydrocodone	Oxalic acid	Triamterene
Cimetidine	Hydrocortisone	Oxazepam	Trifluorperazine
Cis-Tramadol	Hydromorphone	Oxolinic acid	Trimethobenzamide
Clindamycin	p-Hydroxyamphetamine	Oxycodone	Trimethoprim
Clomipramine	o-Hydroxyhippuric acid	Oxymetazoline	Trimipramine
Clozapine	p-Hydroxy-methamphetamine	Oxymorphone	Tryptamine
Cocaine	p-Hydroxynorephedrine	Pamoline	d,l-Tryptophan
Codeine	5-Hydroxytryptamine (Serotonin)	Papaverine	Tyramine
Cortisone	3-Hydroxytyramine (Dopamine)	Penicillin G	d,l-Tyrosine
(-) Cotinine	Hydroxyzine	Pentobarbital	Uric acid
Creatinine		Perphenazine	Vancomycin
Cyclobarbital		Phenelzine	Verapamil
Cyclobenzaprine		Pheniramine	Zomepirac
Deoxycorticosterone			Zopiclone
(-) Deoxyephedrine			

BIBLIOGRAPHY

1. Baselt, Disposition of Toxic Drugs and Chemicals in Man, 6th edition, Biomedical Publications, Foster City, CA.2002. pp 559-562.

INDEX OF SYMBOLS

	Consult Instructions For Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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