KET
One Step Ketamine Test Device (Urine) Package Insert

Cat: KET-102 **Format:** Device
Version: Z **Effective Date:** 2020-07

For professional *in vitro* diagnostic use only.

INTENDED USE

The KET One Step Ketamine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Ketamine in urine at a cut-off concentration of 1000 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 qualitative, 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.

INTRODUCTION

Ketamine is a narcotic drugs and hallucinogens, usually approach to the use of the abuse of cigarettes,inhalants, intravenous or powder into drinks and wine to drink. Usually with heroin, cannabis and other drugs combined, ketamine users easily generate physical dependence, leading to abuse. Generally taking 2-4 hours can be detected.

The KET One Step Ketamine Test Device (Urine) yields a positive result when the concentration of Ketamine inurine exceeds 1000ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The KET One Step Ketamine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs that 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 the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized Ketamine-protein 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 the cut-off level, 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 drug-bovine protein antigen conjugate on the membrane and the conjugate pad of each test contains monoclonal anti-drug antibody.

KIT COMPONENTS

Individually packed Test Devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch 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 totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (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 performing any tests.
- Do not eat, drink or smoke in the area where the 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 the standard procedures for 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.
- The used testing materials should be discarded in accordance with local, state and/or federal 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 until use.
- **Do not freeze.**
- Cares should be taken to protect components in this 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 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.
- Collected urine specimens must be put in clear and dry containers.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 48 hours. 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.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

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

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** (approx. 100 µL) 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 colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

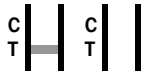
POSITIVE RESULT:

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

NEGATIVE RESULT:

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 RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading 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 the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered negative. Besides, the concentration level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing 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. It confirms 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 One Step Ketamine Test Device (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. Test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS

A. Accuracy

125 clinical urine specimens were analyzed by GC-MS and by the KET One Step Ketamine Test Device (Urine).Each test was performed by three operators. Samples were divided by concentration into five categories: negative, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Method		GC/MS					
The KET One Step Ketamine Test Device		Neg.	Neg. (< – 50% cutoff)	Near cutoff neg. (-50% cutoff to cutoff)	Near cutoff pos. (cutoff to +50% cutoff)	Pos. (> +50 % cutoff)	% agreement with GC/MS
KET 1000	Positive	0	0	1	16	24	97.56%
	Negative	55	14	14	1	0	98.81%

B.Precision

A study was conducted at three physician offices for Ketamine(1000 ng/mL)by professional operators using three different lots of product to demonstrate the within run, between run and between operator precision.An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Drug Conc.	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
Negative	10	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0
-25% Cut-off	10	9	1	9	1	10	0
+25% Cut-off	10	1	9	0	10	1	9
+50% Cut-off	10	0	10	0	10	0	10

C. Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The KET One Step Ketamine Test Device (Urine) was tested in duplicate using fifteen drug free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

D. 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 drugs at 50% below and 50% above cut-off levels. The spiked, pH adjusted urine was tested with the KET One Step Ketamine Test Device (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

E.Cross-Reactivity

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

Ketamine related Compound	Concentration (ng/mL)
Promethazine	25000
Meperidine	50000

F.Non Cross-Reacting Compounds

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

4-Acetamidophenol
Acetaminophen
Acetylsalicylic Acid
Albumin
Amoxicillin
Ampicillin
Ampicillin trihydrate
Aspartame
Atropine
Baclofen
Benzoic Acid
Berberine Chloride Hydrate
Bilirubin
Caffeine
Cephalexin
Cephradine
Chloral hydrate
Chloramphenicol
Chlorpheniramine Maleate
Chlorpromazine
Ciprofloxacin hydrate
Clarithromycin
Clonidine solution
Creatinine
D(-)-Norgestrel
d,l-Propranolol
Deoxycorticosterone
Dextromethorphan solution
Diclofenac
Diflunisal
Digoxin
4-Dimethyl-aminoantipyrine
Diphenhydramine
5,5-Diphenylhydantoin
D-Lactose monohydrate
D-Leucyl-L-tyrosine Hydrate
Dopamine
Droperidol
Enalapril Maleate
Erythromycin
Estradiol
Estrone
Ethyl 4-aminobenzoate
Fluoxetine
Fotemustine
Furosemide
Gabapentin
Gatifloxacin
Gemfibrozil
Gentisic Acid
Gliclazide
Glipizide
Glyburide
Guaiacol
Guaifenesin
Hemoglobin
Hydralazine HCl
Hydrochlorothiazide
Hydrocortisone
Ibuprofen
Isoprenaline
Ketoconazole
Ketoprofen
Lamotrigine
L-Ascorbic acid
Levofloxacin
Lidocaine
Lisinopril Dihydrate
Lithium carbonate
Loperamide
Loratadine
L-Thyroxine sodium
Maprotiline
Meprobamate
Minocycline
Mosapride Citrate
Nalidixic acid
Naloxone HCl
Naltrexone HCl
Naproxen
Nicotinamide
Nicotinic acid
Nifedipine
Nimodipine
Norethisterone Acetate
Norfloxacin Nicotinic
Noscapine
(±)-Octopamine
Ofloxacin
Olanzapine
Oxalic acid, anhydrous
Oxolinic acid
Paliperidone
Pantoprazole sodium
Penfluridol
Penicillin G potassium salt
Penicillin G sodium salt
Perphenazine
Phenacetin
Phenelzine Sulfate
Phenothiazine
2-Phenylethylamine
Pioglitazone
Piracetam
Pravastatin sodium
Prednisone
Procaine
6-Propyl-2-thiouracil
Pyridoxine
Pyrilamine Maleate
Pyrogallic
Quetiapine Fumarate
Quinine
Quinolinic acid
Ranitidine base
Ranitidine
Riboflavin
Rifampicin
Risperidone
Salicylic acid
Sertraline HCl
Simvastatin
Sodium 2-Propylvalerate
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrozoline
Theophylline
Thiamine
Thioridazine solution
Tolbutamide
Topiramate
2,4,7-Triamino-6-Phenylpteridine
Trimethoprim
Tryptamine
Tyramine
Uric acid
(±)-Verapamil
Vitamin B1
Zomepirac

LITERATURE REFERENCES

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
2. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse.* National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols

	Consult Instruction for use		Tests per kit		Do not use if package is damaged
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2℃ 30℃	Store between 2-30°C	LOT	Lot Number	REF	Catalogue number
	Keep away from sunlight		Keep dry		Manufacturer
	Caution		Date of manufacture	EC REP	Authorized Representative

Hangzhou Sejoy Electronics& Instruments Co.,Ltd.
Area C, Building 2, No.365, Wuzhou Road,Yuhang Economic Development Zone,Hangzhou City 311100 Zhejiang China
Website: www.sejoy.com

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

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