

274 mm x 218mm



Insight | KET

Rapid Competitive Immunochromatographic  
Assay for the detection of Ketamine in human  
urine

D E V I C E

DEVICE

#### INTENDED USE

INSIGHT-KET is a rapid, qualitative, immunochromatographic assay for the detection of ketamine in human urine. This test is used to screen the ketamine intoxication. For healthcare professional use only.

#### SUMMARY

Ketamine is a central nervous system (CNS) depressant, used as its hydrochloride salt, it is employed as a general anesthetic for use in human medicine. Ketamine that is known as 'party drug' is abused by many teenagers and young adults. Ketamine can be administered either orally or rectally. It can also be injected or snorted. Ketamine results in impaired attention, difficulty in learning, and impaired memory functions. Higher doses may result in ataxia, dizziness, elevated blood pressure, mental confusion, hyper excitability, hallucinations and psychosis. Long term use of ketamine is associated with hallucinatory flashbacks, an inability to concentrate, psychological dependence and tolerance. Ketamine is excreted in urine and has a half - life of 2.5 to 3 hours.

INSIGHT-KET test detects the presence of ketamine in human urine at 250ng/ml cut-off concentration and above.

#### PRINCIPLE

INSIGHT-KET is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - Agglutinating sera for ketamine conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for ketamine - colloidal gold conjugate complexes with the ketamine present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by ketamine conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result. In absence of ketamine in the test specimen, the Agglutinating sera for ketamine -colloidal gold conjugate and along with rabbit globulin-colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by the ketamine conjugated to BSA coated on the membrane, forming a pink coloured band indicating a negative result.

The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

#### REAGENTS AND MATERIALS SUPPLIED

- A. Each INSIGHT-KET kit contains individual pouches each containing a
1. [DEVICE] : Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Cotinine and rabbit globulin, Cotinine conjugated to BSA and Agglutinating sera for rabbit globulin at the respective regions.
  2. [PIPETTE] : Sample applicator.
  3. Desiccant pouch.
- B. Package insert.

REF	10805010	10805050

#### OPTIONAL MATERIAL REQUIRED

Variable volume precision micropipettes, stopwatch.

#### STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

#### NOTE

1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimen as if potentially infectious.

Insight

5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

#### SPECIMEN COLLECTION AND PREPARATION

1. INSIGHT-KET uses human urine as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. A clean dry plastic or glass container may be used for specimen collection.
4. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
5. Refrigerated specimens must be brought to room temperature prior to testing.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

#### TESTING PROCEDURE

1. Bring the kit components of INSIGHT-KET device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. *Once opened, the device must be used immediately.*
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample applicator vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 50 µl of test specimen into the specimen port (S).
8. Start the stopwatch. Read the results at the end of 5 minutes. Do not interpret the results beyond 8 minutes.

#### INTERPRETATION OF RESULTS

##### Negative Result:



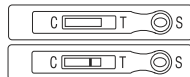
Two pink coloured bands appear at the control region (C) and test region (T). This indicates absence of ketamine in the specimen.

##### Positive Result:



One pink coloured band appears at the control region (C). This indicates that the specimen contains detectable amount of ketamine.

##### Invalid Result:



The test result is invalid if no band appears either at the control region (C) or test region (T). In such cases, verify the test procedure and repeat the test with a INSIGHT-KET device.

Important: A very faint line on the test region indicates that the ketamines in the sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a positive determination is made.

#### REMARKS

1. The deliberate slow reaction kinetics of INSIGHT-KET is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 5 minutes. However, certain samples may take a longer time to flow. Therefore, negatives should be confirmed only at 8 minutes. Do not interpret the results beyond 8 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The assay is designed for use with human urine only.
5. A preliminary positive result indicates only the presence of ketamine and does not indicate or measure the level of intoxication.
6. There is a possibility that technical/or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See specificity section that will produce positive results, or that do not interfere with the test performance.
7. If adulteration is suspected, the test should be repeated with a new sample.

8. Certain over the counter or prescription medications (or certain foods) may cause false results.
9. The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half life, the user's age, weight, activity and diet.
10. **This assay provides only a preliminary analytical test result. 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 Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.**

#### PERFORMANCE CHARACTERISTICS

1. **Sensitivity** : INSIGHT-KET detects ketamine at concentrations equal to or greater than 250ng/ml.
2. **Specificity** : Interference of substances that may be present in urine specimens, as well as effect of sample pH and specific gravity was also studied.
  - a. Cross-reactivity of non-ketamine related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using assay devices.
  - b. No cross-reactivity was detected with the substances listed in table I. Table II lists ketamines related substances and concentrations that produced results approximately equivalent to the cut-off level for ketamines.

**Table I:**

Compounds tested and found not to cross-react with the test at the concentration of 10µl and 100µl in urine.

Acetaminophen	Hemoglobin
Acetone	Ibuprofen
Albumin	(+/-)-Isoproterenol
Ampicillin	Ketamine
Ascorbic Acid	Levorphanol
Aspartame	Lidocaine
Aspirin	(+)-Naproxen
Atropine	Niacinamide
Benzocaine	Nicotine
Bilirubin	(+/-)-Norephedrine
Caffeine	Oxalic Acid
Chloroquine	Penicillin – G
(+)-Chlorpheniramine	Pheniramine
(+/-)-Chlorpheniramine	Phenothiazine
Creatine	1- Phenylethylamine
Dexbrompheniramine	β – Phenylethylamine
Dextromethorphan	Procaine
Diphenhydramine	Quinidine
Dopamine	Ranitidine
(+/-)Epinephrine	Riboflavin
Erythromycin	Sodium Chloride
Ethanol	Sulindac
Furosemide	Theophylline
Glucose	Tyramine
Guaiacol Glycerol Ether	4 – dimethylaminoantipyrine
(1R, 2S)-(-)-N-Methyl-Ephedrine	

**Table II:**

Concentration of ketamine related compounds showing a positive response approximately equivalent to the ketamine cut-off set for the test.

Compound	Concentration in ng/ml
Phencyclidine	>200,000
Norketamine	400
















**WARRANTY**

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

**BIBLIOGRAPHY**

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**SYMBOL KEYS**

	Temperature Limitation		Consult Instructions for use		Date of Manufacture		Do not reuse
	Manufacturer		IVD In vitro Diagnostic Medical Device		This side up		Production site
	Use by		REF Catalogue Number		DEVICE Device		
	Contains sufficient for <n> tests		LOT Batch Number / Lot Number		PIPETTE Disposable Plastic Sample Applicator		



PS

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