KET Surface Test Panel
Package Insert

REF DKE-X14	English

【INTENDED USE】

The KET Surface Test Panel is a rapid immunochromatographic assay for the qualitative detection of Ketamine at the cut-off of 1,000 ng/mL.

With this surface test, you can test:

1. Minimal traces of drugs adhering to surfaces such as furniture, utilitarian objects etc. as residues.
2. Solid substances such as tablets and powder.
3. Urine samples, which can be used to detect drug use.
4. Liquids from ampoules or other containers that may contain suspicious substances.

This assay provides only a preliminary 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.

【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 Ketamine assay contained within the KET Surface Test Panel yields a positive result when the KET concentration exceeds 1,000 ng/mL.

【PRINCIPLE】

During testing, the specimen migrates upward by capillary action. A drug, if present in the specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains membrane strip coated with Ketamine-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Ketamine.

【PRECAUTIONS】

- Use only once.
- Do not touch the free endings of the strip to avoid contamination.
- Do not dip the panel above the maximum deepness level mark.
- Do not spill the samples into the reaction zone.
- Specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Do not use the test after expiration date.
- Do not use the test after damage of the packaging foil.
- Use test right after unwrapping.
- Please take the specificity and the cross reactivity into account for evaluation.
- Store and transport the test device always at 2-30°C.
- **Strong acid, alkali, oxidation and corrosion liquid is not suitable for this test, thick, oily liquid is not suitable for this test.**

【STORAGE AND STABILITY】

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

【MATERIALS】

Materials Provided

- Test panels
- Package insert

Materials Required but Not Provided

- Specimen collection containers
- Timer

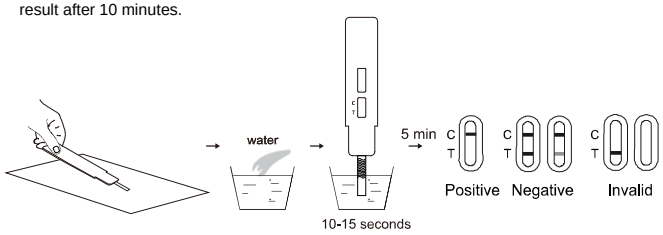
【DIRECTIONS FOR USE】

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

Remove the test panel from the sealed pouch and use it as soon as possible.

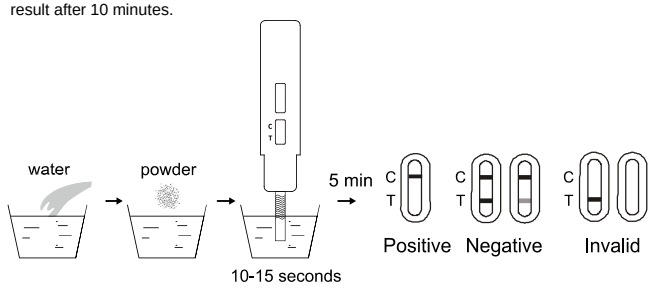
For surfaces:

1. Remove the panel cap and wipe with the panel over the surface in which the drugs are suspected.
2. With the arrow pointing toward the water, **immerse the test panel vertically in the water 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.
3. Wait for the colored lines to appear, **read the results at 5 minutes**. Do not interpret the result after 10 minutes.



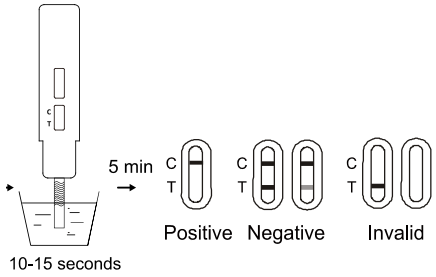
For solids:

1. Prepare specimen collection containers and solid sample.
2. Pour solid sample into the specimen collection containers.
3. At least **1mg solid diluted with 5mL water** (1 mineral water bottle cap≈5mL). Shake to mix well.
4. Remove the panel cap, with the arrow pointing toward the water **immerse the test panel vertically in the diluted 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.
5. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



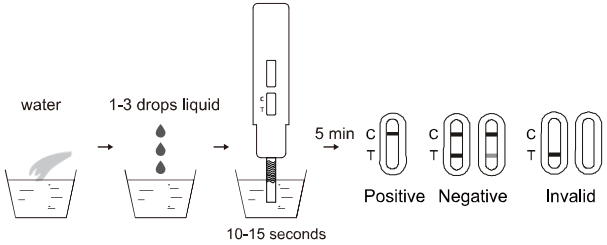
For urine:

1. Collect urine in a clean and dry container.
2. Remove the panel cap, with the arrow pointing toward the specimen, **immerse the test panel vertically in the 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.
3. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



For liquids:

1. Prepare specimen collection containers and liquid sample.
2. Pour **one to three drops of suspicious liquid into 5mL water** (1 mineral water bottle cap≈5mL). Shake to mix well.
3. Remove the panel cap, with the arrow pointing toward the specimen, i**mmerse the test panel vertically in the 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. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the control region (C) and another colored line appears in the test region (T). This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the control region (C) and no line appears in the test region (T). The positive result means that the drug concentration in the sample is greater than the designated cut-off for a specific drug.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Read the directions again and repeat the test with a new test. If the result is still invalid, contact your local distributor.

【QUALITY CONTROL】

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

【LIMITATIONS】

1. The KET Surface Test Panel provides only a qualitative preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.
3. This test does not distinguish between drugs of abuse and certain medications. [1,2]

【PERFORMANCE CHARACTERISTICS】

Accuracy

A comparison was conducted using the KET Surface Test Panel and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
KET Surface 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

The following table lists different concentration drugs that are detected by the KET Surface Test Panel at 5 minutes.

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	15	15

1,250	+25%	30	4	26
1,500	+50%	30	0	30
3,000	300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the KET Surface Test Panel at 5 minutes.

Compound	Concentration (ng/mL)
Ketamine	1,000
Dextromethorphan	1,500
Methoxyphenaminel	12,500
d-Norpropoxyphene	12,500
Promazine	25,000
Promethazine	25,000
Pentazocine	12,500
Phencyclidine	12,500
Tetrahydrozolinel	400
Mephentermine	25,000
(1R, 2S) - (-)-Ephedrine	100,000
Disopyramide	12,500
Benzphetamine	25,000
(+) Chlorpheniramine	25,000
Clonidine	100,000
EDDP	50,000
4-Hydroxyphencyclidine	50,000
Levorphanol	50,000
MDE	50,000
Meperidine	25,000
d-Methamphetamine	25,000
l-Methamphetamine	50,000
3,4-Methylendioxymethamphetamine (MDMA)	100,000
Thioridazine	50,000

Precision

A study was conducted at three sites using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

KET 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
1,250	10	1	9	1	9	2	8
1,500	10	0	10	0	10	0	10

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free or Ketamine positive specimen. The following compounds show no cross-reactivity when tested with the KET Surface Test Panel 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	Phenelzine
Acetylsalicylic acid	Dicyclomine	Iproniazide	Pheniramine
Albumine	Diflunisal	(-) Isoproterenol	l-Phenylephrine
Albuterol	Digitoxin	Isoxsuprine	β-Phenylethylamine
Amantadine	Digoxin	Kanamycin	Phenylpropanolamine
Amikacin	(+) cis-Diltiazem	Ketoprofen	(d,l-Norephedrine)
Aminopyrine	Dimenhydrinate	Labetalol	Prednisolone
Amitriptyline	4-Dimethylaminoantipyrine	Lidocaine	Prednisone
Amobarbital	5,5-Diphenylhydantoin	Lindance	5-β-Pregnane-
Amoxapine	Diphenhydramine	(Hexachlorocyclohexane)	3α,17α,21-triol-20-one
Amoxcilline	Doxylamine	Lithium cacbonate	Procaine
d,l-Amphetamine	Droperidol	Loperamide	Procyclidine
Ampicilline	Ecgonine	Maprotiline	d-Propoxyphene
Apomorphine	Ecgonine methylester	Meprobamate	Protriptyline
Ascorbic acid	Efavirenz (Sustiva)	Methaqualone	d-Pseudoepherine
Aspartame	EMDP	Zomepirac	Quinacrine
Atenolol	Emetine dihydrochloride	Zopiclone	Quinidine
Atropine	hydrate	Methylphenidate	Quinine
Baclofen	(±) Epinephrine	Methyprylon	R-(-) Deprenyl
Benzilic acid	Erythromycine	Metoclopramide	Ranitidine
Benzoic acid	β-Estradiol	Metoprolol	Riboflavin
Benzoylecgonine	Estrone 3 sulfate	Metronidazole	Salbutamol
Bilirubin	Ethanol (Ethyl alcohol)	Morphine-3-β-d	Salicylic acid
Brompheniramine	Ethyl-p-aminobenzoate	glucuronide	Secobarbital
Buprenorphine	(Benzocaine)	Morphine sulfate	Sodium chloride
Buspirone	Etodolac	Nalidixic acid	Spironolactone
Caffeine	Fanprofazone	Nalorphine	Sulfamethazine
Cannabidiol	Fenfluramine	Naloxone	Sulfamethoxazole
Cannabinol	Fenoprofen	Naltrexone	Sulfisoxazole
Carisoprodol	Fentanyl	α-Naphthaleneacetic acid	Sulindac
Cephalexin hydrate	Fluoxetin	Naproxen	Temazepam
Chloral hydrate	Furosemide	Niaciamide	Tetracyline
Chloramphenicol	Gentamicin	Nifedipine	Thebaine
Chlordiazepoxide	Gentisic acid	Nimesulide	Theophylline
Chloroquine	d-(+) Glucose	Norcodein	Thiamine
Chlorothiazide	Guaiacol glyceryl ether	Norethindrone	Thiothixene
Chlorpromazine	(Carbamate)	Norfluoxetine	l-Thyroxine
Chlorpropamide	Haloperidol	Normorphone	Tobramycin
Chlorprothixene	Hemoglobin	Noscapine	Tolbutamide
Cholesterol	Hydralazine	d,l-Octopamine	Trazodone
Cimetidine	Hydrochlorothiazide	Orphenadrine	Triamterene
Cis-Tramadol	Hydrocodone	Oxalic acid	Trifluorperazine
Clindamycin	Hydrocortisone	Oxazepam	Trimethobenzamide
Clomipramine	Hydromorphone	Oxolinic acid	Trimethoprim
Clozapine	p-Hydroxyamphetamine	Oxycodone	Trimipramine
Cocaine	o-Hydroxyhippuric acid	Oxymetazoline	Tryptamine
Codeine	(-) Deoxyephedrine	Oxymorphone	d,l-Tryptophan
Cortisone	Hydroxyzine	Pamoline	Tyramine
(-) Cotinine	p-Hydroxynorephedrine	Papaverine	d,l-Tyrosine
Creatinine	5-Hydroxytryptamine	Penicillin G	Uric acid
Cyclobarbital	(Serotonin)	Pentobarbital	Vancomycin
Cyclobenzaprine	3-Hydroxytyramine	Perphenazine	Verapamil
Deoxycorticosterone	(Dopamine)		
trans-2-Phenyl-	(±) 3,4-Methylendioxy-	p-Hydroxy-	
cyclopropylamine	nphetamine (MDA)	ethamphetamine	

【BIBLIOGRAPHY】

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Edition. Biomedical Publications, Foster City, CA. 2002; 744-747.

2. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	30°C 2°C	Temperature limit
	Caution	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use
	Manufacturer				

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