™Synthetic Marijuana (K2) Surface Test Panel

Package Insert

REF DSM-X14	English

【INTENDED USE】

The Synthetic Marijuana (K2) Surface Test Panel is a rapid immunochromatographic assay for the qualitative detection of K2 at the cut-off of 50 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】

Synthetic Marijuana or K2 a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

The K2 assay contained within the Synthetic Marijuana (K2) Surface Test Panel yields a positive result when the K2 concentration exceeds 50 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 strips coated with Synthetic Marijuana-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 K2.

【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

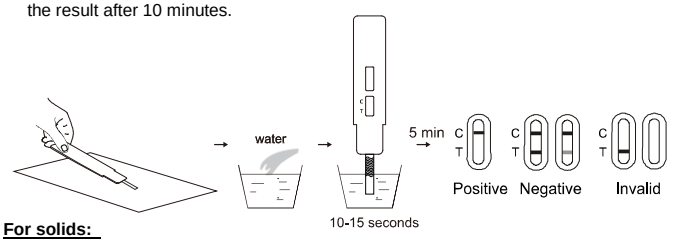
【DIRECTIONS FOR USE】

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.

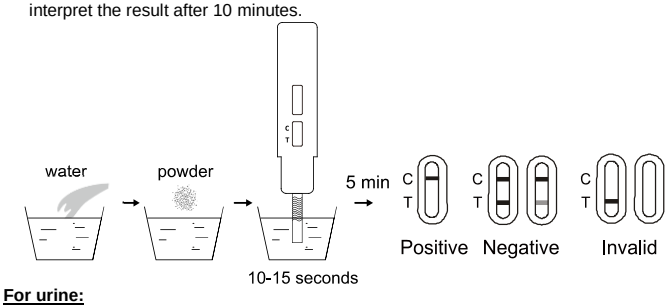
For surfaces:

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.



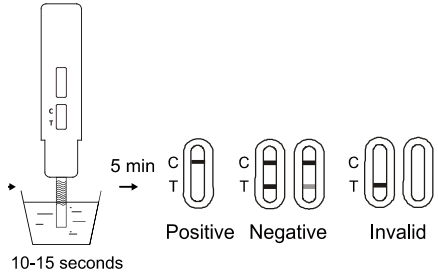
For solids:

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.



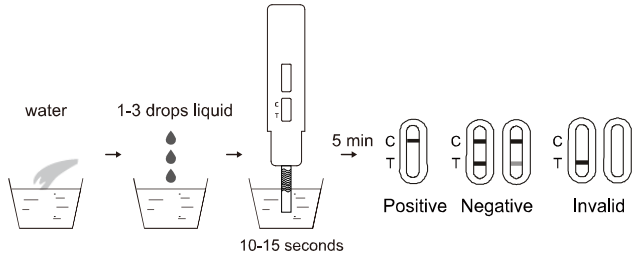
For urine:

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 colored 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 Synthetic Marijuana (K2) 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 Synthetic Marijuana (K2) Surface Test Panel and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
Synthetic Marijuana (K2) Surface Test Panel	Results	Positive	Negative	
	Positive	90	10	100
	Negative	6	144	150
Total Results		96	154	250
% Agreement		93.8%	93.5%	93.6%

Analytical Sensitivity

The following table lists different concentration drugs that are detected by the Synthetic Marijuana (K2) Surface Test Panel at 5 minutes.

K2 Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
25	-50%	30	30	0
37.5	-25%	30	27	3

50	Cut-off	30	15	15
62.5	+25%	30	3	27
75	+50%	30	0	30
150	300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the Synthetic Marijuana (K2) Surface Test Panel at 5 minutes.

Compound	Concentration (ng/mL)
JWH-018 5-Pentanoic acid	50
JWH-073 4-butanoic acid	50
JWH-018 4-Hydroxypentyl	400
JWH-018 5-Hydroxypentyl	500
JWH-073 4-Hydroxybuty	500

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:

K2 Concentration (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	8	2	8	2	9	1
62.5	10	2	8	2	8	1	9
75	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 K2 positive specimen. The following compounds show no cross-reactivity when tested with the Synthetic Marijuana (K2) Surface Test Panel at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetaminophenol	4-Dimethylaminoantipyrine	Maprotiline	Procaine
Acetone	Diphenhydramine	Meperidine	Promazine
Acetophenetidin	5,5-Diphenylhydantoin	Meprobamate	Promethazine
N-Acetylprocainamide	Disopyramide	d-Methamphetamine	l-Propoxyphene
Acetylsalicylic acid	Doxylamine	l-Methamphetamine	d,l-Propranolol
Albumin	Ecgonine	Methadone	d-Pseudoephedrine
Amitriptyline	Ecgonine methylester	Methoxyphenamine	Quinacrine
Amobarbital	EMDP	(+)-3,4-Methylendioxy-	Quinidine
Amoxapine	Ephedrine	Methylphenidate	Quinine
Amoxicillin	l-Ephedrine	Mephentermine	Ranitidine
Ampicillin	l-Epinephrine	Metoprolol	Riboflavin
Ascorbic acid	Morphine-3-β-D-glucuronide	(±)-Epinephrine	Salicylic acid
Aminopyrine	Erythromycin	Morphine sulfate	Serotonin
Apomorphine	β-Estradiol	Methyprylon	(5-Hydroxytryptamine)
Aspartame	Estrone-3-sulfate	Nalidixic acid	Sodium chloride
Atropine	Ethanol (Ethyl alcohol)	Nalorphine	Sulfamethazine
Benzilic acid	Ethyl-p-aminobenzoate	Naloxone	Sulindac
Benzoic acid	Etodolac	Naltrexone	Sustiva (Efavirenz)
Benzphetamine	α-Naphthaleneacetic acid	Famprofazone	Temazepam
Bilirubin	Fentanyl	Naproxen	Tetracycline
Brompheniramine	Fluoxetine	Niacinamide	Tetrahydrocortexolone
Buspirone	Furosemide	Nifedipine	Tetrahydrocortisone,
Cannabinol	Gentisic acid	Nimesulide	3-acetate
Cimetidine	d-Glucose	Norcodeine	Tetrahydrozoline
Chloral hydrate	Guaiacol glyceryl ether	Norethindrone	Thebaine
Chloramphenicol	Hemoglobin	d-Norpropoxyphene	Thiamine
Chlordiazepoxide	Hydralazine	Noscapine	Thioridazine
Chloroquine	Hydrochlorothiazide	d,l-Octopamine	l-Thyroxine
Chlorothiazide	Hydrocortisone	Orphenadrine	Tolbutamide
(+)-Chlorpheniramine	o-Hydroxyhippuric acid	Oxalic acid	cis-Tramadol
(±)-Chlorpheniramine	p-Hydroxymethamphetamine	Oxazepam	trans-2-
Chlorpromazine	3-Hydroxytyramine	Oxolinic acid	Phenylcyclopropylamine
Chlorprothixene	(Dopamine)	Oxycodone	Trazodone
Cholesterol	Hydroxyzine	Oxymetazoline	Trimethobenzamide
Clomipramine	Ibuprofen	Oxymorphone	Triamterene
Codeine	Imipramine	Papaverine	Trifluoperazine
Cortisone	Iproniazide	Pemoline	Trimethoprim
(-)-Cotinine	(-)-Isoproterenol	Penicillin-G	Trimipramine
Creatinine	Isoxsuprine	Pentazocine	Tryptamine
Cyclobarbital	Kanamycin	Perphenazine	d,l-Tryptophan
Cyclobenzaprine	Ketamine	Phencyclidine	Tyramine
Deoxycorticosterone	Ketoprofen	Phenelzine	d,l-Tyrosine
R (-)Deprenyl	Labetalol	Pheniramine	Uric acid
Dextromethorphan	Levorphanol	Phenobarbital	Verapamil
Diazepam	Lidocaine	Phenothiazine	Digoxin
Diclofenac	Lindane	Phentermine	Lithium carbonate
Dicyclomine	(Hexachlorocyclohexane)	Prednisolone	l-Phenylephrine
Diflunisal	Loperamide	Prednisone	Procaine
4-Acetaminophenol	4-Dimethylaminoantipyrine	Maprotiline	Promazine
Acetone	Diphenhydramine	Meperidine	Promethazine
Acetophenetidin	5,5-Diphenylhydantoin	Meprobamate	d-Pseudoephedrine
4-Acetaminophenol	4-Dimethylaminoantipyrine	Maprotiline	Procaine
Acetone	Diphenhydramine	Meperidine	Promazine
Acetophenetidin	5,5-Diphenylhydantoin	Meprobamate	Promethazine
Disopyramide	N-Acetylprocainamide	d-Methamphetamine	l-Propoxyphene
Acetylsalicylic acid	Doxylamine	l-Methamphetamine	d,l-Propranolol
Albumin	Ecgonine	Methadone	

【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		Contains sufficient for <n> tests		Temperature limit
	Caution		Batch code		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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Number: 145342004
Revision date: 2023-09-19