SCREEN®

Synthetic Marijuana (K2) Rapid Test Panel (Urine) Package Insert

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

【INTENDED USE】

The Synthetic Marijuana (K2) Rapid Test Panel (Urine) is a rapid chromatographic immunoas say for the detection of Synthetic Marijuana metabolite in human urine. The syntheticmariju- ana detected by the test includes, but are not limited to, the metabolites of JWH-018 and JWH -073.

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/ma ss 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】

Synthetic Marijuana or K2 is 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.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1,2011,five cannabinoids,JWH-018,JWH-073,CP-47, JWH-200 and cannabicyclo hexanol 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 Synthetic Marijuana 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 synthetic marijuana metabolite in human urine. The Synthetic Marijuana Rapid Test Strip (Urine) yields a positive result when the synthetic marijuana metabolite in urine exceeds 50 ng/mL.

【PRINCIPLE】

The K2 Rapid Test Panel (Urine) is an 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. Synthetic Marijuana metabolite, if present in the urine specimen below 50ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized synthetic marijuana 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 Synthetic Marijuana metabolite level exceeds 50ng/mL because it will saturate all the binding sites of anti- Synthetic Marijuana antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, 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 panel contains mouse monoclonal anti- synthetic marijuana antibody-coupled particles and synthetic marijuana -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 STABILITY】

Store as packaged in the sealed pouch either 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 testing. 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

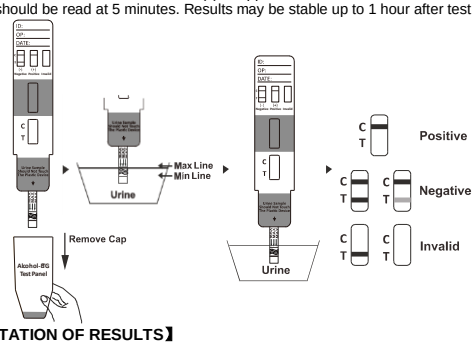
Materials Required But Not Provided

- Specimen collection container
- 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 as soon as possible.
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. Results may be stable up to 1 hour after test initiation.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two 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). A negative result indicates that the Synthetic Marijuana metabolite concentration is below the detectable level (50ng/mL).

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

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A positive result indicates that the Synthetic Marijuana metabolite concentration exceeds the detectable level (50ng/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 testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The K2 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. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the synthetic marijuana metabolite concentration is below the detectable level of 50ng/ml. Positive result means the concentration of synthetic marijuana metabolite is above the level of 50ng/ml. The K2 Rapid Test Panel has a sensitivity of 50ng/ml

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the K2 Rapid Test Panel (Urine) and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
K2 Rapid Test Panel	Results	Positive	Negative	
	Positive	78	3	81
	Negative	2	167	169
Total Results		80	170	250
% Agreement		97.5%	98.2%	98.0%

Analytical Sensitivity

A drug-free urine pool was spiked with K2 at the following concentrations: 0、25、37.5、50、62.5、75 and 150ng/mL. The results demonstrate >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Synthetic Marijuana 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	26	4
50	Cut-off	30	15	15
62.5	+25%	30	3	27
75	+50%	30	0	30
150	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the K2 Rapid Test Panel (Urine) at 5 minutes.

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

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 synthetic marijuana, 25%synthetic marijuana above and below the cut-off, and 50% synthetic marijuana above and below the 50ng/mL cut-off was provided to each site. The following results were tabulated:

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	1	9	2	8	2	8
75	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 25ng/mL and 75ng/mL of synthetic marijuana. The K2 Rapid Test Panel (Urine) was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity (1.005-1.045) 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 synthetic marijuana to 25ng/mL and 75ng/mL. The spiked, pH-adjusted urine was tested with the K2 Rapid Test Panel (Urine) in duplicate. The results demonstrated that varying ranges of pH do 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 synthetic marijuana positive urine. The following compounds show no cross-reactivity when tested with the K2 Rapid Test Panel (Urine) 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	(±)-Epinephrine	Morphine-3-β-D-glucuronide	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	Famprofazone	α-Naphthaleneacetic acid	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	

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