Synthetic Marijuana (K2) Card 008Q103

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 *Drug*Control **K2 Test** is a rapid chromatographic immunoassay for the detection of Synthetic Marijuana metabolite in human urine. The synthetic marijuana detected by the test includes, but are not limited to, the metabolites of JWH-018 and JWH-073. The following table lists compounds that are positively detected in urine by the *Drug*Control **K2 Test** at 5 minutes:

TEST DEVICE	CALIBRATOR / related compounds	CUT-OFF LIMIT VALUE [ng / ml]
K2 50	**JWH-073 4-butanoic acid metabolite**	**50**
	JWH-018 5-Pentanoic acid metabolite	**50**
	JWH-018 4-Hydroxypentyl metabolite	400
	JWH-018 5-Hydroxypentyl metabolite	500
	JWH-073 4-Hydroxybutyl metabolite	500

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.

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 *Drug*Control **K2 Test** 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 *Drug*Control **K2 Test** yields a positive result when the synthetic marijuana metabolite in urine exceeds 50 ng/mL.

TEST PRINCIPLE

The *Drug*Control **K2 Test** 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 strip 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 device should remain in the sealed pouch until use.
- Do not use the test if the foil pouch is damaged
- Do not moisten nitrocellulose membrane with urine samples.
- Read the entire procedure carefully prior testing.
- 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.
- Humidity and temperature can adversely affect results.
- The used test device should be discarded according to federal state and local regulations.
- Do not reuse tests
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.

STORAGE AND STABILITY

Store as packaged 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. Tests should be kept out of direct sunlight.

- 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.

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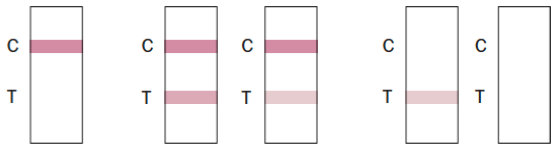
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS PROVIDED
- Test in pouch
- Disposable sample dropper (in pouch)
- Package insert

MATERIALS REQUIRED, BUT NOT PROVIDED
- Specimen collection container
- Timer
- Positive and negative controls

DIRECTIONS FOR USE
1. **Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.**
2. Bring the pouch to room temperature before opening it.
3. Remove the Test from the sealed pouch and use it within one hour.
4. Place the test cassette on a clean and level surface.
5. Hold the dropper vertically and transfer 3 full drops of urine to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
6. Read results at 5 minutes. Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS



Positive: One color line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the K2 concentration is above the detectable cut-off level. (substances & cut-off concentrations see table on page 1).

Negative:* Two lines appear. One color line should be in the control region (C), and another apparent color line should be in the test region (T). This negative result indicates that the K2 concentration is below the detectable cut-off level.

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 with a new test. If the problem persists, discontinue using the test immediately and contact your local distributor.

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

QUALITY CONTROL
A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

LIMITATIONS
- The ***Drug*Control K2 Test** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (GC/MS) is the preferred confirmatory method[1,2].
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- This test does not distinguish between drugs of abuse and certain medications.
- The ***Drug*Control K2 Test** is intended for use with human urine specimens only.

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 ***Drug*Control K2 Test** has a sensitivity of 50ng/ml

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PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the ***Drug*Control K2 Test** and GC/MS. The following results were tabulated:

K2		***GC/MS***		***Total Results***
		Positive	*Negative*	
***Drug*Control** K2 Test	*Positive*	*78*	*3*	*81*
	Negative	*2*	*167*	*169*
Total Results		*80*	*170*	*250*
% Agreement with this Test		***97.5%***	***98.2%***	***98.0%***

Analytical Sensitivity

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

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

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 HPLC, 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 ***Drug*Control K2 Test** was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity 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 4 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 ***Drug*Control K2 Test** 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 ***Drug*Control K2 Test** at a concentration of 100 µg/mL.

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Non Cross-Reacting Compounds

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

LIMITATIONS

It is impossible to check any and all - other than those drugs mentioned in the product insert - for cross-reactivity or any other influences to the to be detected drug of abuse (DOA).
If the patient takes a „cocktail“ of several different drugs or medication cannot be excluded that a non-reproducible cross-reaction can falsified the test result.

BIBLIOGRAPHY

1. Wong, R., the Current Status of Drug Testing in the US Workforce, Am.Clin.Lab, 2002; 21(1):21-23
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4. Wong, R., the Effect of Adulterants on Urine Screen for Drugs of Abuse: Detection by an On-site Dipstick Device, Am.Clin.Lab, 2002; 21(3); 14-18
5. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982.
6. Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Expiration date
	Read instructions for use		Store at
	Keep away from direct sunlight	REF	Ordering number
	Keep dry		

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

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