Synthetic Marijuana (K2) Rapid Test Cassette (Whole blood/Serum/Plasma)

Package Insert

REF DSM-402	English

A rapid test for the qualitative detection of synthetic marijuana in human whole blood or serum or plasma.

For medical and other professional in vitro diagnostic use only.

【INTENDED USE】

The Synthetic Marijuana (K2) Rapid Test Cassette (whole blood /serum/plasma) is a rapid chromatographic immunoassay for the detection of Synthetic Marijuana metabolite in human whole blood/serum/plasma. The synthetic marijuana 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/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 whole blood/serum/plasma metabolites are found within hours of exposure and remain detectable window up to 24-48 hours after smoking (depending on usage/dosage). The K2 assay contained within the K2 Rapid Test Cassette yields a positive result when the K2 concentration in whole blood / serum / plasma exceeds 100ng/ml.

【PRINCIPLE】

The K2 Rapid Test Cassette (whole blood /serum/plasma) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the whole blood /serum/plasma specimen compete against the drug conjugate for binding sites on the antibody. During testing, a whole blood /serum/plasma specimen migrates upward by capillary action. Synthetic Marijuana metabolite, if present in the whole blood /serum/plasma specimen below 100ng/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 100ng/ml because it will saturate all the binding sites of anti- Synthetic Marijuana antibodies.

A drug-positive whole blood /serum/plasma specimen will not generate a colored line in the test line region, while a drug-negative whole blood /serum/plasma 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 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】

- The K2 Rapid Test Cassette can be performed using whole blood/serum/plasma (from venipuncture or fingerstick).
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 40 μl. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen area of the test cassette.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. For long term storage, specimens should be kept below -20°C. Whole blood/serum/plasma collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood or serum or plasma specimens. Whole blood/serum/plasma collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

【MATERIALS】

Materials Provided

• Test cassettes • Droppers • Buffer • Package insert

Materials Required But Not Provided

• Specimen collection containers • Centrifuge
•lancets (for fingerstick whole blood only) • Timer
•Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature (15-30°C) before opening it. Remove the cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.

For serum or plasma specimen:

•Hold the dropper vertically and transfer **1 full drop of serum or plasma** (approximately 40ul), then add **2 drops of buffer** (approximately 80 μl) to the specimen well(S) of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.

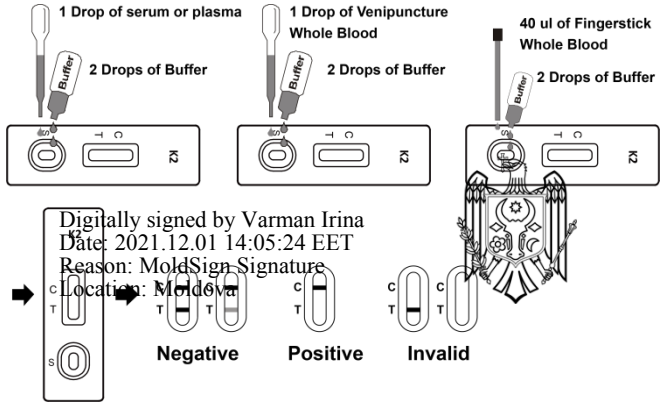
For Venipuncture Whole blood specimen:

•Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 40μl) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 μl), and start the timer. See illustration below.

For Fingerstick Whole blood specimen:

•To use a capillary tube: Fill the capillary tube and **transfer approximately 40μl of fingerstick whole blood specimen** to the specimen well(S) of test cassette, then add **2 drops of buffer**(approximately 80 μl) and start the timer. See illustration below.

3. Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not interpret the result after 10 minutes.



【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 (100ng/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 (100ng/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 Cassette (whole blood/serum/plasma) 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 whole blood/serum/plasma specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in whole blood/serum/plasma specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another whole blood/serum/plasma 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 whole blood/serum/plasma.
5. A negative result may not necessarily indicate drug-free whole blood/serum/plasma. 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 100ng/ml. Positive result means the concentration of synthetic marijuana metabolite is above the level of 100ng/ml. The K2 Rapid Test Cassette has a sensitivity of 100ng/ml.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the K2 Rapid Test Cassette (whole blood/serum/plasma) and GC/MS. The following results were tabulated:

Clinic Result of Whole Blood

Method		GC/MS		Total Results
K2 Rapid Test Cassette	Results	Positive	Negative	
	Positive	21	2	23
	Negative	2	65	67
Total Results		23	67	90
% Agreement		91.3%	97.0%	95.6%

Clinic Result of Serum or Plasma

Method		GC/MS		Total Results
K2 Rapid Test Cassette	Results	Positive	Negative	
	Positive	21	2	23
	Negative	2	65	67
Total Results		23	67	90
% Agreement		91.3%	97.0%	95.6%

Analytical Sensitivity

A drug-free whole blood/serum/plasma pool was spiked with Cocaine at the following concentrations of ±50%cutoff and 3x cutoff , the data are summarized below:

For whole blood:

Synthetic Marijuana Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
50	-50%	30	30	0
100	Cut-off	30	15	15
150	+50%	30	0	30
300	3X	30	0	30

For serum or plasma:

Synthetic Marijuana Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
50	-50%	30	30	0
100	Cut-off	30	15	15
150	+50%	30	0	30
300	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in whole blood/serum/plasma by the K2 Rapid Test Cassette (whole blood/serum/plasma) at 5 minutes.

Compound	Concentration (ng/ml)
JWH-018 5-Pentanoic acid metabolite	100
JWH-018 4-Hydroxypentyl metabolite	800
JWH-018 5-Hydroxypentyl metabolite	1000
JWH-073 4-Hydroxybutyl metabolite	1000
JWH-073 4-butanoic acid metabolite	100

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, 50% synthetic marijuana above and below the 100ng/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
50	10	8	2	9	1	9	1
150	10	1	9	1	9	2	8

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either

drug-free whole blood/serum/plasma or synthetic marijuana positive whole blood/serum/plasma. The following compounds show no cross-reactivity when tested with the K2 Rapid Test Cassette (whole blood/serum/plasma) at a concentration of 100µg/ml.

Non Cross-Reacting Compounds

Acetominophen	Diazepam	Methadone	Prednisone
Acetophenetidin	Diclofenac	Methoxyphenamine	Procaine
N-Acetylprocainamide	Diflunisal	(±)-3,4-Methylenedioxy-	Promazine
Acetylsalicylic acid	Digoxin	amphetamine	Promethazine
Aminopyrine	Diphenhydramine	(±)-3,4-Methylenedioxy-	D,l-Propranolol
Amitryptyline	Doxylamine	methamphetamine	D-Propoxyphene
Amobarbital	Ecgonine methylester	Morphine-3- -D	D-Pseudoephedrine
Amoxicillin	(-)-ψ-Ephedrine	glucuronide	Quinidine
Ampicillin	Erythromycin	Morphine Sulfate	Quinine
l-Ascorbic acid	-Estradiol	Nalidixic acid	Ranitidine
D,l-Amphetamine sulfate	Estrone-3-sulfate	Naloxone	Salicylic acid
Apomorphine	Ethyl-p-aminobenzoate	Naltrexone	Secobarbital
Aspartame	Fenoprofen	Naproxen	Serotonin
Atropine	Furosemide	Niacinamide	Sulfamethazine
Benzilic acid	Gentisic acid	Nifedipine	Sulindac
Benzoic acid	Hemoglobin	Norcodein	Temazepam
Benzphetamine	Hydralazine	Norethindrone	Tetracycline
Bilirubin	Hydrochlorothiazide	D-Norpropoxyphene	Tetrahydrocortisone,
(±) -Brompheniramine	Hydrocodone	Noscapine	3-Acetate
Caffeine	Hydrocortisone	D,l-Octopamine	Tetrahydrocortisone
Cannabidiol	O-Hydroxyhippuric acid	Oxalic acid	3-(-D glucuronide)
Cannabinol	p-Hydroxy-	Oxazepam	Tetrahydrozoline
Chloralhydrate	methamphetamine	Oxolinic acid	Thebaine
Chloramphenicol	3-Hydroxytyramine	Oxycodone	Thiamine
Chlordiazepoxide	Ibuprofen	Oxymetazoline	Thioridazine
Chlorothiazide	Imipramine	Papaverine	D,l-Tyrosine
(±) -Chlorpheniramine	Iproniazid	Penicillin-G	Tolbutamide
Chlorpromazine	(±) - Isoproterenol	Pentobarbital	Triamterene
Chlorquine	Isoxsuprine	Perphenazine	Trifluoperazine
Cholesterol	Ketamine	Phencyclidine	Trimethoprim
Clomipramine	Ketoprofen	Phenelzine	Trimipramine
Clonidine	labetalol	Phenobarbital	Tryptamine
Codeine	levorphanol	Phentermine	D,l-Tryptophan
Cortisone	loperamide	l-Phenylephrine	Tyramine
(-) Cotinine	Maprotiline	-Phenylethylamine	Uric acid
Creatinine	Meperidine	Phenylpropanolamine	Verapamil
Deoxycorticosterone	Meprobamate	Prednisolone	Zomepirac

Interfering Substances

The K2 Rapid Test Cassette (whole blood/serum/plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. In addition, no interference was observed in specimens containing up to 100 mg/dl hemoglobin;up to 100 mg/dl bilirubin; and up to 200 mg/dl human serum albumin.

【BIBLIOGRAPHY】

1. Wong, R., the Current Status of Drug Testing in the US Workforce, Am.Clin.Lab, 2002; 21(1):21-23
2. Info Facts -Club drugs, NIDA, May 2006, http://www.nida.nih.gov/infofacts/clubdrugs.html

Index of Symbols

	Consult Instructions For Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P. R. China
www.alltests.com.cn

EC REP
MedNet GmbH
Borkstrasse 10
48163 Muenster
Germany

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