



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

REF DSM-101 English

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 Dipstick (Urine) 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.

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 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 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 Synthetic Marijuana Rapid Test Dipstick (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 Dipstick (Urine) yields a positive result when the synthetic marijuana metabolite in urine exceeds 30ng/mL.

PRINCIPLE

The K2 Rapid Test Dipstick (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 30ng/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 30ng/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 dipstick 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 Dipsticks
- Package insert

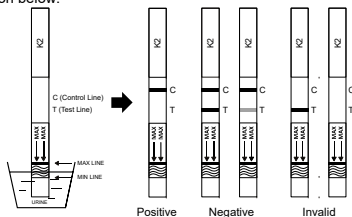
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and use it within one hour.
- With arrows pointing towards the urine specimen, immerse the Test Dipstick vertically in the urine specimen in such a way that urine does not cross MAX line on the Test Dipstick for 10-15 seconds. See the illustration below.



- Wait for the color line(s) to appear. The result should be read 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 (30ng/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 (30ng/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

- The K2 Rapid Test Dipstick (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}
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- 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 30ng/mL. Positive result means the concentration of synthetic marijuana metabolite is above the level of 30ng/mL. The K2 Rapid Test Dipstick has a sensitivity of 30ng/mL.

PERFORMANCE CHARACTERISTICS

Accuracy

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

| Method | GC/MS | | Total Results |
|------------------------|----------|----------|---------------|
| | Positive | Negative | |
| K2 Rapid Test Dipstick | 82 | 2 | 84 |
| | 2 | 164 | 166 |
| Total Results | 84 | 166 | 250 |
| % Agreement | 97.6% | 98.8% | 98.4% |

Analytical Sensitivity

A drug-free urine pool was spiked with K2 at the following concentrations: 0 ng/mL, 15 ng/mL, 22.5 ng/mL, 30 ng/mL, 37.5 ng/mL, 45 ng/mL, and 90 ng/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 |
| 15 | -50% | 30 | 30 | 0 |
| 22.5 | -25% | 30 | 27 | 3 |
| 30 | Cut-off | 30 | 16 | 14 |
| 37.5 | +25% | 30 | 4 | 26 |
| 45 | +50% | 30 | 0 | 30 |
| 90 | 3X | 30 | 0 | 30 |

Analytical Specificity

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

| Compound | Concentration (ng/mL) |
|-------------------------------------|-----------------------|
| JWH-018 5-Pentanoic acid metabolite | 30 |
| JWH-073 4-butanoic acid metabolite | 30 |
| JWH-018 4-Hydroxypentyl metabolite | 250 |
| JWH-018 5-Hydroxypentyl metabolite | 300 |
| JWH-073 4-Hydroxybutyl metabolite | 300 |

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 30ng/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 | 0 | 0 | 0 | 0 | 10 | 0 |
| 15 | 10 | 10 | 0 | 10 | 0 | 10 | 0 |
| 22.5 | 10 | 8 | 2 | 9 | 1 | 9 | 1 |
| 37.5 | 10 | 1 | 9 | 1 | 9 | 1 | 9 |
| 45 | 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 15ng/mL and 45ng/mL of synthetic marijuana. The K2 Rapid Test Dipstick (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 15ng/mL and 45ng/mL. The spiked, pH-adjusted urine was tested with the K2 Rapid Test Dipstick (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 Dipstick (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 |
| Amiripityline | Ecgonine methylester | Methoxyphenamine | Quinacrine |
| Amobarbital | EMDP | (+)-3,4-Methylenedioxy- | Quinidine |
| Amoxapine | Ephedrine | Methylphenidate | Quinine |
| Amoxicillin | l-Ephedrine | Mephentermine | Ranitidine |
| Ampicillin | l-Epinephrine | Metoprolol | Riboflavin |
| Ascorbic acid | (±)-Epinephrine | Morphine | 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) | Naloxone | Sulfamethazine |
| Benzilic acid | Ethyl-p-aminobenzoate | Naltrexone | Sulindac |
| Benzoic acid | Etodolac | α-Naphthaleneacetic acid | Sustiva (Efavirenz) |
| Benzphetamine | Famprofazone | α-Naphthaleneacetic acid | Temazepam |
| Bilirubin | Fentanyl | Naloxone | Tetracycline |
| Brompheniramine | Fluoxetine | Niacinamide | Tetrahydrocortexolone |
| Buspirone | Furosemide | Nifedipine | Tetrahydrocortisone, |
| Cannabinol | Gentisic acid | Nimesulide | 3-acetate |
| Cimetidine | d-Glucose | Norcodeine | Tetrahydrozoline |
| Chloral hydrate | Guaiaicol glyceryl ether | Norethindrone | Thebaine |
| Chloramphenicol | Hemoglobin | d-Norpropoxyphene | Thiamine |
| Chloridiazepoxide | 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 | Phenylcyclopropylamine |
| Chlorpromazine | 3-Hydroxytyramine | Oxolinic acid | Trazodone |
| Chlorprothixene | (Dopamine) | Oxycodone | Trimethobenzamide |
| Cholesterol | Hydroxyzine | Hydroxyzoline | Triamterene |
| Clomipramine | lbutrofen | Oxymorphone | Trifluoperazine |
| Codaine | Imipramine | Papaverine | Trimethoprim |
| Cortisone | lproniazide | Penicillin | Trimipramine |
| (-)-Cotinine | (-)-Isoproterenol | Penicillin-G | Tryptamine |
| Creatinine | Isoxsuprine | Pentazocine | d,l-Tryptophan |
| Cyclobarbital | Kanamycin | Perphenazine | Tyramine |
| Cyclobenzaprine | Ketamine | Phencyclidine | d,l-Tyrosine |
| Deoxycorticosterone | Ketoprofen | Phenelzine | Uric acid |
| R (-)Deprenyl | Labetalol | Pheniramine | Verapamil |
| Dextromethorphan | Levorphanol | Phenobarbital | Digoxin |
| Diazepam | Lidocaine | Phenothiazine | Lithium carbonate |
| Diclofenac | Lindane | Pertemine | l-Phenylephrine |
| Dicyclomine | (Hexachlorocyclohexane) | Prednisolone | Procaine |
| Diffunisal | Loperamide | Prednisone | Promazine |
| 4-Acetaminophenol | 4-Dimethylaminoantipyrine | Maprotiline | Promethazine |
| Acetone | Diphenhydramine | Meperidine | |
| Acetophenetidin | 5,5-Diphenylhydantoin | Meprobamate | |

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Index of Symbols

| | | | | | |
|--|-------------------------------------|--|---------------|--|---------------------------|
| | Attention, see instructions for use | | Tests per kit | | Authorized Representative |
| | For in vitro diagnostic use only | | Use by | | Do not reuse |
| | Store between 2-30°C | | Lot Number | | Catalog # |
| | Do not use if package is damaged | | | | |

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