

One Step Synthetic Cannabis (K2) Urine Test

Catalog No. See Pouch Label

One Step Synthetic Cannabis (K2) Urine Test is a rapid one step test for the qualitative detection of Synthetic Cannabis JWH-018 and JWH-073 in human urine at or above the cut-off level of 50ng/ml.

For in vitro diagnostic use only. For forensic use only.

INTENDED USE

The One Step *Synthetic Cannabis (K2)* Urine Test is a lateral flow chromatographic immunoassay for the detection of *Synthetic Cannabis JWH-18 and JWH-73* in human urine at a cut-off level of 50ng/ml. 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 cannabis is a psychoactive designer drug derived of natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis. It is best known by the brand names K2 and Spice. Synthetic cannabis act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. A large and complex variety of synthetic cannabis most often cannabicyclohexanol, JWH-018, JWH-073, or HU-210, are used in an attempt to avoid the laws that make cannabis illegal, making synthetic cannabis a designer drug Although synthetic cannabis does not produce positive results in drug tests for cannabis, it is possible to detect its metabolites in human urine. The synthetic cannabinoids contained in synthetic cannabis products have been made illegal in many European countries. On November 24, 2010, the U.S. Drug Enforcement Administration announced it would use emergency powers to ban many synthetic cannabinoids within a month. As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47,497, JWH-200, and cannabicyclohexanol are now illegal in the US.

PRINCIPLE

One Step Synthetic Cannabis (K2) Urine Test is a competitive immunoassay that is used to screen for the presence of Synthetic Cannabis (K2) in urine. It is chromatographic absorbent device in which Synthetic Cannabis JWH-018 and/or JWH-073 in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- This kit is for external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiry date.
- Do not use the kit if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- Do not read after 5 minutes
- This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

- 25 tests per kit., one test in one pouch.
- One pouch containing a test and a desiccant. The only desiccant is for storage purposes only, and is not used in the test procedures.
- Leaflet with instructions for use.

STORAGE AND STABILITY

Store at 4 ~ 30 °C in the sealed pouch up to the expiration date. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

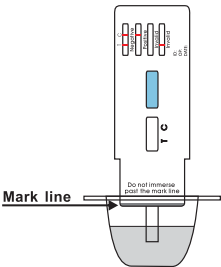
SPECIMEN COLLECTION AND PREPARATION

Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below). Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (18°C to 30° C)

- Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
- Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
- Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the “MAX” line printed on the front of the device.
- Lay the device flat on a clean, dry, non-absorbent surface.
- Read the result at 5 minutes. **Do not read after 5 minutes.**



INTERPRETATION OF RESULTS

Positive (+)

A rose-pink band is visible in the control region. No color band appears in the appropriate test region. It indicates that JWH-018 or JWH-073 concentration is equal to or higher than the detection limit(50 ng/ml).

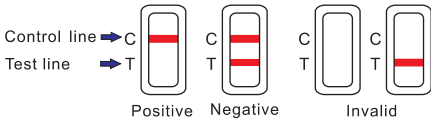
Negative (-)

A rose-pink band is visible in the control region and the appropriate test region. It indicates that the JWH-018 or JWH-073 concentration is zero or below the detection limit (50 ng/ml).

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

- This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
- Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by the One Step Synthetic Cannabis (K2) Urine Test. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	1	17	22
Negative	22	18	0	0

% agreement among positives is 100% (95% Confidence Interval 84.5% - 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 74.5% - 100%)

Viewer B:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	17	22
Negative	22	18	1	0

% agreement among positives is 97.5% (95% Confidence Interval 82% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

Viewer C:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	15	22
Negative	22	18	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77% - 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5% - 100%)

From the results of the above tables, the total results are showed as below:

The average positive agreement is 96.7%

The average negative agreement is 99.2%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, and the cutoff + 50%. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot.

Lot 1

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
25	90	90/0
38	90	76/14
50	90	43/47
63	90	12/78
75	90	0/90

Lot 2

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
25	90	90/0
38	90	76/14
50	90	43/47
63	90	12/78
75	90	0/90

Lot 3

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
25	90	90/0
38	90	76/14
50	90	43/47
63	90	12/78
75	90	0/90

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test Synthetic Cannabis (K2), drug metabolites and other components of the same class that are likely to be present in urine, All the components were added to drug-free normal human urine. These concentrations below also represent the limits of detection for the specified drugs or metabolites.

Component	Concentration (ng/ml)
JWH-018	50
JWH-073	50

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with JWH-018 or JWH-073 at 50% below and 50% above cutoff level. One step Synthetic Cannabis (K2) Urine test was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with JWH-018 or JWH-073 at 50% below and 50% above cutoff levels. One step Synthetic Cannabis (K2) urine test was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds show no cross-reactivity when tested with One Step Synthetic Cannabis (K2) Urine Test at a concentration of 100 µg/ml.

Acetaminophen	Lidocaine Hydrochloride
Acetate prednisone	Lisinopril Tabelets
Acetylcodeine	Lithim Carbonate
Aciclovir Tablets	Lofexidine hydrochloride
Adanon	Loperamide Hydrochloride
Adenosine monophosphate	Loratadine Tablets
Alprazolam	Lutein/Zeaxanthin
Aminophylline	Magnesium
Amiodarone Hydrochloride	Maleate fluvoxamine
Amitriptyline hydrochloride	Manganese
Amlodipine Mesylate	Meperidine hydrochloride
Ampicillin	Methadone hydrochloride
Ampicillin Sodium	Methyl amphetamine
Anitidine hydrochloride	Metoprolol Tartrate
Aripiprazole	Mifepristone Tablets
Aspirin	Mirtazapine
Atomoxetine	Mogadan
Atorvastatin Calcium	Monoacetylmorphine
Atropine Sulfate	Montelukast Sodium
Barbitone	Morphine
Benzoylecgonine	Mosapride Citrate
Biotin	Nalbuphine HCl.
Caffeine	Naloxone HCL
Calcium	Niacin
Captopril Tablets	Nifedipine Tablets
Carbamazepine	Nikethamide
Carbohydrate	Nimodipine Tablets
Cefaclor	Nitroglycerin Tablets
Cefradine	Olanzapine Tablets
Cephalexin	Omeprazole
Chlorphenamine Maleate	Oxazepam
Chlorpheniramine maleate	Oxycodone hydrochloride
Chlorpromazine	Paliperidone
Chlorpromazine Hydrochloride	Pantoprazole
Chondroitin sulfate	Papaverine
Cimetidine	Paracetamol Tablets
Ciprofloxacin Hydrochloride	Paroxetine hydrochloride
Clarithromycin Capsules	Penfluridol
Clomipramine hydrochloride	Perphenazine
Clopidogrel Hydrogen Sulphate	Phenoxymethylpenicillin Potassium
Clozapine Tablets	Phentolamine
Cocaine hydrochloride	Phenylephrine HCL
Codeine phosphate	Phenylethyl barbirtuic acid
Conjugated Estrogens	Phenytoin
Copper	Pholcodine
Dextromethorphan HBr	phytosterols
Dextromethorphan hydrobromide	Pioglitazone Hydrochloride
Dextropropoxyphene napsilate	Piracetam
DHEA	Potassium
Diazepam	pravastatin sodium
Diclfenac Sodium	Prednisone
Digoxin	Pregnenolone
Diphenhydramine HCL	procaine hydrochloride
Diphenoxylate hydrochloride	Propranolol Hydrochloride
Dirithromycin	Propylthiouracil Tablets
Dommperidone Tablets	Pseudoephedrine hydrochloride

Dopamine hydrochloride
Doxepin hydrochloride
Doxylamine
Duloxetine hydrochloride
Enalapril Maleate Tablets
Ephedrine hydrochloride
Escitalopram
Esomeprazole Magnesium
Fenofibrate
Fentanyl citrate
Flunitrazepam
Fluoxetine Hydrochloride
Folic acid
FurosemideTablets
Gabapentin
Glibenclamide Tablets
Gliclazide Tablets
Glipizide
Glucosamine hydrochloride
Glucose
Haloperidol
Hydrochlorothiazide
Hydrocortisone butyrate
Isoprenaline
Isosorbide Dinitrate
Ketamine Hydrochloride
Ketoconazole Tablets
Lamotrigine tablets
Lansoprazole Tablets
Levofloxacin Hydrochloride
Levonorgestrel Tablets
Levothyroxine sodium
4-Acetamidophenol
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitriptyline
Amobarbital
Amoxicillin
Ampicillin
Ascorbic acid
D,L-Amphetamine
L-Amphetamine
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Billirubin
Brompheniramine
Caffeine
Chloralhydrate
Paliperidone
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diffunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride

Quetiapine Fumarate
Ranitidine Hydrochloride
Reserpine
Riboflavin
Rifampicin Capsules
Risperidone
Secobarbital
selenium
Sertraline Hydrochloride
Sildenafil Citrate
Simvastatin
Sodium
Sodium valproate
Spironolactone Tablets
Sulfate hydralazine
Tetracycline Tablets
Thebaine
Topiramate
Tramadol hydrochloride
Trazodone hydrochloride
Triamterene
Venlafaxine hydrochloride
Vitamin A
Vitamin B1
Vitamin B12
Vitamin B2
Vitamin B6
Vitamin C
Vitamin D
Vitamin E
Zinc

Methoxyphenamine
(+) 3,4-Methylenedioxyamphetamine
(+)-3,4-Methylenedioxyamphetamine
Methylphenidate
Methpyrlyon
Morphine-3-β -Dglucuronide
Nalorphine
Naloxone
Nalidixic acid
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
p-Hydroxymethamphetamine
Papaverine
Penicillin-G
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β -Phenylethlamine
β -Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
Procaine
Promazine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine

Ecgonine methylester
(-) Y Ephedrine
Erythromycin
β -Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric acid
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(-) Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Levorphanol
Loperamide
Maprotiline
Meprobamate
Methadone

Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3 Acetate
Tetrahydrocortisone3 (5-Dglucuronide)
Tetrahydrozoline
Thebaine
Thiamine
Thioridazine
D, L-Thyroxine
Tolbutamine
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tryptophan
Tyramine
PrD, L-Tyrosine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY OF SUGGESTED READING

1. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
2. Urine Testin for Drugs of Abuse, National Institute on Drug Abuse (NIDA) research monograph 73, 1986
3. Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
4. BJum, K., Handbook of Abuseable Drugs, Gardner Press, Inc., New York, NY 1 st Ed., 1984
5. Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
6. Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

Index of Symbols

	For <i>in vitro</i> diagnostic use only		Store between 4 ~ 30 °C
	Do not reuse		Manufacturer
	Keep away from sunlight		Keep dry