One Step K2 Drug of Abuse Test

(Dip Card)

For Forensic Use Only

INTENDED USE

The ***One Step K2 Drug of Abuse Test*** is a lateral flow chromatographic immunoassay for the qualitative detection of synthetic cannabinoids metabolites in human urine specimen at the cut-off level of 50ng/mL and 20ng/mL. This assay is intended for forensic use only.
This assay provides only a preliminary qualitative test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

Since 2004, herbal mixtures such as 'Spice' have been sold in Switzerland, Austria, Germany and other European countries mainly via Internet shops. Although declared as incense, they are smoked as 'bio-drugs' by the consumers. In corresponding blogs, drug users reported cannabis-like effects after smoking. These products enjoy great popularity particularly among younger people, as up to now the mixtures are sold in head shops and via internet in many countries without age restriction. [1] JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. [2] JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", and K3". [3] These products may be smoked for their psychoactive effects.

Synthetic Cannabinoids (K2 50)
The ***One Step K2 Drug of Abuse Test*** yields a positive result when synthetic cannabinoid compounds in urine exceed 50ng/mL.

Synthetic Cannabinoids (K2 20)
The ***One Step K2 Drug of Abuse Test*** yields a positive result when synthetic cannabinoid compounds in urine exceed 20ng/mL.

PRINCIPLE

The ***One Step K2 Drug of Abuse Test*** is an immunoassay based on the principle of competitive binding. Drug which may be present in the urine specimen competes against their respective drug conjugate for binding sites on their specific antibody.
During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.
A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.
To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been applied and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugate (purified bovine albumin) at the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal K2 antibody.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- Use of gloves is recommended to avoid unnecessary contact with the specimen.
- The used test device and urine specimen should be discarded according to federal, state and local regulations.
- The test is for single use.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2°C - 30°C (36°F - 86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

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 precipitates should be allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimen collected for later testing may be stored at 2°C - 8°C (36°F - 46°F) for up to 48 hours. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

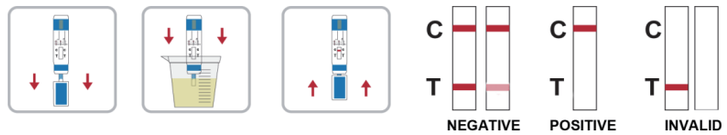
MATERIALS

Materials Provided:
- Test device
- Desiccants
- Package insert

Materials Required But Not Provided:
- Specimen collection container
- Disposable gloves
- Timer

INSTRUCTIONS FOR USE

1) Remove the test device from the foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for 5 seconds. Urine sample should not touch the plastic device.
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorptive clean surface.
5) Read result at 5 minutes
DO NOT INTERPRET RESULT AFTER 10 MINUTES.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
NEGATIVE: Two lines appear. * One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative even if there is a faint distinguishable color line.

POSITIVE: One color line appears in the control region (C) while no line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable 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 using a new test device. If the problem persists, discontinue using the lot immediately and contact your supplier.

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, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The ***One Step K2 Drug of Abuse Test*** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. A positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
4. 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.
5. If adulteration is suspected, the test should be repeated with another new urine specimen and a new test device.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the ***One Step K2 Drug of Abuse Test*** was evaluated in comparison to liquid chromatography/mass spectrometry (LC/MS) or gas chromatography/mass spectrometry (GC/MS). 60 specimens comprised of 20 negative urine samples and 40 positive urine samples for 50ng/mL For 20ng/mL, it comprised of 22 negative urine samples and 38 positive urine samples.They were blinded and tested with the ***One Step K2 Drug of Abuse Test*** and compared to LC/MS or GC/MS results. The testing showed a ≥95% agreement between two methods.

Synthetic Cannabinoids (K2 50)

Analyte		Positive Urine Sample	Negative Urine Sample	Total Results
K2 50	Positive	39	0	39
	Negative	1	20	21
Total Urine Samples		40	20	60
% Agreement		97.5%	>99%	--

Synthetic Cannabinoids (K2 20)

Analyte		Positive Urine Sample	Negative Urine Sample	Total Results
K2 20	Positive	37	0	37
	Negative	1	22	23
Total Urine Samples		38	22	60
% Agreement		97.4%	>99%	--

Precision

A study was conducted in an effort to determine the precision of the ***One Step K2 Drug of Abuse Test.*** Testing was conducted using three different lots of product to demonstrate the within-run and between-run precision. The correlation with expected results for the solutions targeted to +/-50% of the cut-off was > 99% across all lots.

Synthetic Cannabinoids (K2 50)

JWH-018 and JWH-073 Concentration (ng/mL)	Number of Test Samples Per Lot	Positive			Negative		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
No Drug Present	20	0	0	0	20	20	20
25	20	0	0	0	20	20	20
75	20	20	20	20	0	0	0

Synthetic Cannabinoids (K2 20)

JWH-018 and JWH-073 Concentration (ng/mL)	Number of Test Samples Per Lot	Positive			Negative		
		Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
No Drug Present	20	0	0	0	20	20	20
10	20	0	0	0	20	20	20
30	20	20	20	20	0	0	0

PN: Y031113060Z

Analytical Sensitivity

Synthetic Cannabinoids (K2 50)
The cut-off concentration (sensitivity level) of K2/Spice test is determined to be 50ng/mL of JWH-018 Pentanoic Acid Metabolite and 50ng/mL of JWH-073 Butanoic Acid Metabolite respectively. Tests were ran in 10 replicates with negative urine and standard control at ±25% cut-off and ±50% cut-off concentration levels. Test results are summarized below.

Percent of Cut-off K2 Concentration in ng/mL		n	Test Result	
			Negative	Positive
0% Cut-off	(No Drug Present)	10	10	0
-50% Cut-off (25ng/mL)	JWH-018 Pentanoic Acid	10	10	0
	JWH-073 Butanoic Acid	10	10	0
-25% Cut-off (37.5ng/mL)	JWH-018 Pentanoic Acid	10	10	0
	JWH-073 Butanoic Acid	10	10	0
Cut-off (50ng/mL)	JWH-018 Pentanoic Acid	10	0	10
	JWH-073 Butanoic Acid	10	0	10
+25% Cut-off (62.5ng/mL)	JWH-018 Pentanoic Acid	10	0	10
	JWH-073 Butanoic Acid	10	0	10
+50% Cut-off (75ng/mL)	JWH-018 Pentanoic Acid	10	0	10
	JWH-073 Butanoic Acid	10	0	10

Synthetic Cannabinoids (K2 20)
The cut-off concentration (sensitivity level) of K2/Spice test is determined to be 20ng/mL of JWH-018 Pentanoic Acid Metabolite and 20ng/mL of JWH-073 Butanoic Acid Metabolite respectively. Tests were ran in 10 replicates with negative urine and standard control at ±25% cut-off and ±50% cut-off concentration levels. Test results are summarized below.

Percent of Cut-off K2 Concentration in ng/mL		n	Test Result	
			Negative	Positive
0% Cut-off	(No Drug Present)	10	10	0
-50% Cut-off (10ng/mL)	JWH-018 Pentanoic Acid	10	10	0
	JWH-073 Butanoic Acid	10	10	0
-25% Cut-off (15ng/mL)	JWH-018 Pentanoic Acid	10	8	2
	JWH-073 Butanoic Acid	10	8	2
Cut-off (20ng/mL)	JWH-018 Pentanoic Acid	10	3	7
	JWH-073 Butanoic Acid	10	3	7
+25% Cut-off (25ng/mL)	JWH-018 Pentanoic Acid	10	2	8
	JWH-073 Butanoic Acid	10	3	7
+50% Cut-off (30ng/mL)	JWH-018 Pentanoic Acid	10	0	10
	JWH-073 Butanoic Acid	10	0	10

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the ***One Step K2 Drug of Abuse Test*** at a reading time of 5 to 10 minutes.

Compound	**Concentration (ng/mL)**
JWH-018 5-pentanoic acid metabolite	20ng/mL
JWH-073 4-butanoic acid metabolite	20ng/mL
MAM2201 N-pentanoic acid metabolite	200ng/mL
JWH-398 N-pentanoic acid metabolite	400ng/mL
JWH-210 N-(5-carboxypentyl) metabolite	2, 500ng/mL
JWH-073 3-hydroxybutyl metabolite	2, 500ng/mL
JWH-018 N-4-hydroxypentyl	8, 000ng/mL
JWH-073 4-hydroxybutyl metabolite	40, 000ng/mL
JWH-019 5-hydroxyhexyl metabolite	40, 000ng/mL
JWH-018 5-hydroxypentyl metabolite	45, 000ng/mL
JWH-122 5-hydroxypentyl metabolite	50, 000ng/mL
JWH-122 4-hydroxypentyl metabolite	50, 000ng/mL
JWH-019 6-hydroxyhexyl metabolite	50, 000ng/mL
RCS-4 N-(5-carboxypentyl) metabolite	50, 000ng/mL
Trifluoperazine dihydrochloride	50, 000ng/mL
Trifluoperazine hydrochloride	70, 000ng/mL
2,4,6-Trimethylbenzamide	100, 000ng/mL

EFFECT OF SPECIMEN SPECIFIC GRAVITY

The urine samples of normal, high, and low specific gravity ranges from 1.000-1.025 were spiked with drugs at 50% below and 50% above cut-off levels respectively and tested using ***One Step K2 Drug of Abuse Test.*** The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test

EFFECT OF SPECIMEN PH

The pH of an aliquot negative urine pool was adjusted to pH ranges of 4.5 - 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the ***One Step K2 Drug of Abuse Test.*** The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

INTERFERENCE

A study was conducted to determine the interference of the test with compounds in either drug-free urine or drug positive urine containing K2. The following compounds show no interference when tested with the ***One Step K2 Drug of Abuse Test*** at concentrations of 100µg/mL.

(-)-11-nor-9-carboxy-delta-9-THC
(-)-delta-9-THC
(+/-) Nicotine
(+/-)-11-nor-9-carboxy-delta-9-THC
(+/-)-4-Hydroxyamphetamine HCL
(1R,9S)-(-)-β-Hydrastine
11-Hydroxy-delta-9-THC
1-Naphthylacetic Acid1
2,3-Pyridine Dicarboxylic Acid
4-Metylumbelliferyl B-D-Glucuronide Hydrate
5,5-Diphenylhydantoin
Acebutolol
Acetaminophen
Acetazolamide
Acetone
Acetophenetidin
Acetopromazine－d6
Acetyl-L-Cysteine
Acetylsalicylic Acid (Aspirin)
a-Chymotrypsin
a-Hydroxyalprazolam
a-Hydroxyhippuric Acid
Albumin, Human Recombinant
Allopurinol
Alphenal
Alprazolam
Alprenolol Hydrochloride
Amantadine Hydrochloride
Amikacin
Amikacin Sulfate
Amiloride
Aminophenazon
Aminophylline
Amiodarone Hydrochloride
Amitriptyline
Ammonium Chloride
Amobarbital
Amoxicillin
Amphetamine Sulfate
Amphotericin B
Ampicinine(Ampicillin)
Anamycin Sulfate
Aniline
Antipyrine
Apomorphine
Aprobarbital
Aspartame
Atenolol
Atropine
Baclofen
Barbituric Acid
Beclometasone Dipropionate
Beclomethasone
Bendroflumethiazide
Benzalkonium Bromide
Benzilic Acid
Benzocaine
Benzoic Acid
Benzoylecogonine
Benzphetamine
Benzthiazide
Benzyl Alcohol
Benzylamine Hydrochloride
Berberine
Betamethasone
Bilirubin
Bisacodyl
Bromazepam
Bromocriptine Mesylate
Bupivacaine
Buprenorphine
Bupropion Hydrochloride
Buspirone
Butabarbital
Butacaine
Butalbital
Butethal
Butyrophenone
Caffeine
Camphor
Cannabidiol
Canrenoic Acid
Captopril
Carbamazepine
Carisoprodol
Cefaclor
Cefadroxil
Cefotaxime
Cefoxitin
Cefradine Capsules
Ceftriaxone
Cefuroxime Axetil (Zinnat)
Cephradine
Cetirizine Hydrochloride
Chloral Hydrate
Chloramphenicol
Chlordiazepoxide HCL
Chloroquine
Chlorothiazide
Chlorotrianisene
Chlorpheniramine
Chlorpromazine
Chlorpropamide
Chlorprothixene
Chlorthalidone
Chlorzoxazone
Cholesterol
Cicosporin
Cimetidine
Cinchonidine
Cinoxacin
Citric Acid
Clenbuterol Hydrochloride
Clindamycin
Clobazam
Clobetasone Butyrate
Clomipramine
Clonazepam
Clonidine Hydrochloride
Clorazepate Dipotassium
Cloxacillin
Clozapine
Cocaethylene
Cocaine Hydrochloride
Codeine
Colchicine
Compound Zinc Undec
Cortisone
Cotinine
Creatinine
Cyclobenzaprine Hydrochloride
Cyclopentobarbital
Cyclophosphamide
Cyproheptadine Hydrochloride
D/L-Tyrosine
Dantrolene Sodium
D-Aspartic Acid
Deferoxamine Mesylate
Delta-8-THC
Deoxyepinephrine
Desipramine
Desoximetasone
Dexamethasone
Dextromethorphan Hydrobromide
Diazepam
Diazoxide
Dieldrin
Diflorasone Diacetate
Diflunisal
Digoxin
Dihydralazine
Dimethyl Isosorbide
Dimethyl Sulfoxide
Dipyridamole
Dipyrone
Disopyramide
DL-3,4-Dihydroxymandelic Acid
DL-Aminoglutethimide
DL-Aspartic Acid
DL-Tryptophan
D-Methamphetamine
Dobutamine
Dopamine
Doxepin
Doxycycline Hytclate
Doxylamine
Droperidol
Ecgonine Methylester
Emetine Dihydro-Chloride Hydrate
Ephedrine-(+/-)
Erythromycin
Eserine
Estazolam
Estradiol,17B-
Estriol
Estrone
Estrone-3-Sulfate
Ethacrynic Acid
Ethambutol
Ethyl Acetate
Ethylenediamine Tetraacetic Acid
Ethyl Morphine
Ethyl-p-aminobenzoate
Etodolac
Etoposide
Famotidine
Fenfluramine
Fenoprofen
Fentanyl Citrate Salt
Ferrous Sulfate
Flufenamic Acid
Flunisolide
Flunitrazepam
Fluphenazine Dihydrochloride
Flurandrenolide
Flurazepam
Furosemide
Gemfibrozil
Gentamicin Sulfate
Gentisic Acid
Glucose
Glutathione Reduced
Glybenclamide
Griseofulvin
Halcinonide
Haloperidol
Hemoglobin
Heroin
Hexachlorophene
Hippuric Acid
Histamine
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
Hydroflumethiazide
Hydromorphone
Hydroxocobalamin
Hydroxyprogesterone
Hydroxyurea
Hydroxyzine Dihydrochloride
Hypnoval（Cyclobarbital）
Hypoxanthine
Ibuprofen
Imidazole
Imipramine
Indapamide
Indomethacin
Ipratropium Bromide
Isonicotinic Acid

Isoproterenol-(+/-)
Isoxsuprine
JWH-210 4-hydroxypentyl metabolite
Ketamine
Kynurenic Acid
Labetalol
Lactose
L-Aspartic Acid
L-Cystine
Levorphanol
Lidocaine
Lisinopril
Lithium Carbonate
Loperamide
Lorazepam (±) /Lorazepam Glucuronide
L-Thyroxine
Mannitol
Maprotiline
Mebendazole
Meclofenamic Acid
Medazepam
Mefenamic Acid
Melanin
Menthol
Meperidine
Meprobamate
Merperidine
Metaproterenol Hemisulfate Salt
Metaraminol
Methadone
Methamphetamine
Methoxamine
Methoxyamine Hydrochloride
Methoxyphenamine
Methyl Salicylate
Methylene Blue
Methylenedioxymethamphetamine-(+/-) 3/4（MDMA）
Methylphenidate
Meticrane
Metoclopromide Hydrochloride
Metronidazole
Mianserin
Midazolam
Milrinone
Minaprine
Morphine
Nabumetone
N-Acetylprocainamide
Nadolol
Nafcillin
Nalbuphine
Nalidixic Acid
Nalmefene
Nalorphine Hydrochloride
Naloxone Hydrochloride
Naltrexone Hydrochloride
Naphazoline Hydrochloride
Naphthol
Naproxen
Neomycin Sulfate
Niacinamide
Nialamide
Nicotinic Acid
Nifedipine
Nimesulide
Nitrazepam
Nitrofurantoin
Nomifensine
Norchlordiazepoxide
Norclomipramine
Norcocaine
Nordiazepam
Nordoxepin
Norethindrone
Norfloxacin
Norfludiazepam
Norpropoxyphene
Nortriptyline Hydrochloride
Noscapine
Nylidrin
O6-Acetylmorphine
Octopamine
Ofloxacin
Orphenadrine Hydrochloride
Oxalic Acid
Oxazepam
Oxycodone
Oxymetazoline
Oxymorphone
Oxyphenbutazone
Oxypurinol
Paclitaxel
p-Aminobenzoic Acid
Pancuronium Bromide
Papaverine
Paracetamol Tablets
Pargyline
PCP Morpholine Anolog
Penicillin
Pentobarbital
Pentoxifylline
Pentylenetetrazole
Perphenazine
Phenacetin
Phencyclidine (PCP)
Phenelzine
Phenformin
Pheniramine
Phenobarbital
Phenol
Phenolphthalien
Phenothiazine
Phentermine
Phenylbutazone
Phenylephrine-L
Phenylethylamine
Phenylpropanolamine
Phenyltoloxamine
p-Hydroxymethamphetamine
Picrotoxin
Pilocarpine
Pimozide
Pipecolic Acid
Piroxicam
Potassium Chloride
Potassium Iodide
p-Phenylene
Prazepam
Prazosin
Prednisolone Acetate
Prednisone
Prilocaine
Primaquine diphosphate
Primidone
Proadifen
Probenecid
Procainamide Hydrochloride
Procaine
Prochlorperazine Dimaleate Salt
Procyclidine
Promazine
Promethazine
Propionylpromazine
Propoxyphene,d-
Propranolol
Protriptyline
Pseudoephedrine HCL
Pyridine-2-Aldoxime
Pyridoxine
Pyrilamine
Quinacrine
Quinidine
Quinine
R(-)-Epinephrine
Ranitidine
Riboflavin
Ritodrine
Roxithromycin Tablets
Salbutamol (Albuterol)
Salicylic Acid
Secobarbital
Serotonin
Sertraline
Sodium Chloride
Sodium Cromoglicate
Sodium Formate
Stearic Magnesium
Sulfamethazine
Sulfamethoxazole
Sulfanilamide
Sulfathiazole
Sulindac
Tamoxifen Citrate
Tannic Acid
Temazepam
Tenoxicam
Terbutaline
Terfenadine
Tetracycline
Tetraethylthiuram Disulfide
Tetrahydrocannabinol, Delta-9-
Tetrahydrozoline
Thebaine
Theobromine
Theophylline
Thiamine
Thioridazine Hydrochloride
Tobramycin
Tolazamide
Tolbutamide
Tolmetin
Tramadol
Trans-2-Phenylcyclo-Propylamine Hydrochloride
Trazodone
Triazolam
Trichlormethiazide
Trichloroacetic Acid
Trimethoprim
Trimipramine
Triprolidine
Tropic Acid
Tropine
Tryptamine
Tyramine
Urea
Uric Acid
Vancomycin HCL
Vanillic acid Diethylamine
VB2
Venlafaxine Hydrochloride
Verapamil
Vincamine
Xylometazoline
Yohimbine
Zearalenone
Zomepirac
Zopiclone

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