

K2 drug test (cassette)

Intended use

K2 Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of synthetic cannabis JWH-18 and JWH-73's major metabolites in human urine specimens at cut-off level of 25 ng/ml. This assay has not been evaluated in the point of care location and is for use by Healthcare Professionals only.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated

Principle Of The Test

K2 Test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between drug conjugate and free drug which may be present in the urine specimen being tested. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Reagents And Materials Provided

1. Instructions for use.
2. K2 Test: The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-rabbit IgG antibody.
Test zone: contains K2 protein antigen conjugates.
Control zone: contains Goat anti-rabbit IgG antibody.
Conjugate pad: contains Mouse anti-K2 monoclonal antibody.

Materials Required But Not Supplied

1. Urine collection container.
2. Timer or clock.

Storage

Store the test device at 2 to 30° C. Do Not Freeze.

Specimen Collection And Preparation

It is required that approximately 120 - 150 µl of sample for each test. Fresh urine specimens do not need any special handling or treatment. Specimens should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately,

urine specimen may be refrigerated at 2-8°C or frozen up to 7 days. Specimens should be thawed and brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

Assay Procedure

For Test Card

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 µl) of sample in to the sample well.
5. Read the results at 5 to 10 minutes after adding the sample.

Test results may not be accurate after 10 minutes.

Quality Control

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within established range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

The K2 Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

Interpretation of Results

Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result indicates that the concentrations of metabolites of JWH-18 and/or JWH-73 in the specimen is either zero or less than cut-off level.

Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the concentrations of metabolites of JWH-18 and/or JWH-73 in the specimen is above the cut-off level.

Invalid:

If there is no colored band in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A borderline (+/-) in test line zone should be considered negative result.

Expected Values

K2 Test is a qualitative assay. It identifies JWH-018 pentanoic acid or JWH-073 butanoic acid in human urine at a concentration of 25 ng/ml or higher. The concentration of the synthetic cannabis cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

Sensitivity

The cut-off concentration (sensitivity level) of K2) Test is determined to be 50 ng/ml of JWH-018 5-pentanoic acid metabolite and JWH-73 4-butanoic acid metabolite respectively.

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Specificity

The specificity for K2 Test test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The K2 Test performance at cut-off level is not affected when pH and

Specific Gravity ranges of urine specimen are at 5.0 to 8.0 and 1.005 to 1.035.

The following substances were tested and confirmed not to interfere with K2 Test at the listed concentrations.

Glucose 2000 mg/dL

Human albumin 2000 mg/dL

Human hemoglobin 10 mg/dL

Urea 4000 mg/dL

Uric acid 10 mg/dL

2. Specificity

K2 Test is specific with JWH-018 pentanoic acid and JWH-073 butanoic acid.

Compounds	Concentration	Cross-reactivity
JWH-018 pentanoic acid	25ng/ml	100%
JWH-073 butanoic acid	25ng/ml	200%
MAM2201 N-pentanoic acid	100ng/ml	50%
JWH-398 N-pentanoic acid	200ng/ml	25%
JWH-210 N-(5-carboxypentyl)	300ng/ml	17%

Each listed substance that may be found in the urine was evaluated and indicated negative result at concentration of 100 µg/ml or higher unless it is specified.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic Acid
Amitriptyline	Amobarbital	Amphetamine
Aspartame	Ascorbic acid	Atenolol
Atrophine	Benzoyllecgonine	Buprenorphine
Butabarbital	Butalbital	Caffeine
Cannabidiol	Cannabinal	Cetirizine
Cortisone	Chlorpheniramine	Cocaine
Cotinine	Despiramine	Dextromethorphan
Digitoxin	Digoxin	Diphenhydramine
Doxylamine	Ecgonine	Ecgonine methyl ester
Ephedrine	Epinephrine	Fentanyl
Gentisic acid	Guaiacol glycer ester	Heroin
Homatrophine	Hydrochlorothiazide	Hydroxyzine
Imipramine	Isoproterenol	Ketamine
MDA	MDMA	Meperidine
Methamphetamine	Methadol	Methadone
Morphine	Nalbuphine	Nalorphine
Natrexone	Neomycin	Niacinamide
Noigertaline	Nortriptyline	Orphenadine
Oxycodone	Oxymorphone	Perphenazine
Pentobarbital	Phencyclidine (PCP)	Phenobarbital
Phenylpropanolamine	Promethazine	Propranolol
Protriptyline	Quetiapine fumarate	Quinine antidine
Salicylic acid	Secobarbital	Sertal
Tetracycline	Tetrahydrozoline	Theophylline
Trifluoperazine	Trihexyphenidyl	Trimipramine
Tyramine	Venlafaxine	Verapamil
11-nor- Δ^8 -THC-9-COOH(10 μ g/ml)*	11-nor- Δ^9 -THC-9-COOH(10 μ g/ml)*	

Accuracy

The accuracy of the K2 Test was evaluated in K2 spiked urine specimens. Forty K2 urine specimens were spiked with JWH-018 pentanoic acid or JWH-73 butanoic acid from 10 to 150 ng/ml. 30 samples with JWH-018 pentanoic acid or JWH-073 butanoic acid concentration between 25 and 150 ng/mL were all found positive (100% agreement), 10 samples with JWH-018 pentanoic acid or JWH-073 butanoic acid concentration between 10 and 18.75 ng/mL were found negative.

Precision

The precision study was performed by three individuals observing the test result to determine the random error of visual interpretation. The test results were found to have no significant differences between the three observers.

Device	Control con. ng/ml	No. of Tested	No. of positive			No. of borderline #			No. of negative		
			1*	2*	3*	1*	2*	3*	1*	2*	3*
JWH-018 pentanoic acid	0	42							42	42	42
	25	42							42	42	42
	75	42	40	41	40	2	1	2			

Precautions

1. Do not use the product beyond the expiration date.
2. Handle all specimens as potentially infectious.
3. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
4. Use a new urine specimen cup for each sample to avoid cross contamination.
5. The test device should be stored at 4 to 30°C and will be effective until the expiration date stated on the package.
6. The product is humidity-sensitive and should be used immediately after being open.
7. Any improperly sealed product should be discarded.

Limitations

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.

There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

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