K2

CE

One Step K2 Test Cassette (Urine)

Package Insert

This Instruction Sheet is for testing of K2/Spice Synthetic Cannabinoid
A rapid, one step test for the qualitative detection of single drug and its metabolites in human urine.
For forensic use only.

INTENDED USE

The One Step K2 Test Strip (Urine) is a lateral flow chromatographic immunoassay for the detection of *single drug and its metabolites* in human urine.

Test	Calibrator	Cut-off
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50 ng/mL

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

Since 2004, herbal mixtures such as 'Spice' are 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.
JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", K3" and others. These products may be smoked for their psychoactive effects.
The One Step K2 Drug of Abuse Test yields a positive result when K2 synthetic cannabinoid in urine exceed 50ng/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 compete 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 at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugate (purified bovine albumin) on 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 strip 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 strip should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip 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 strips
- Package insert

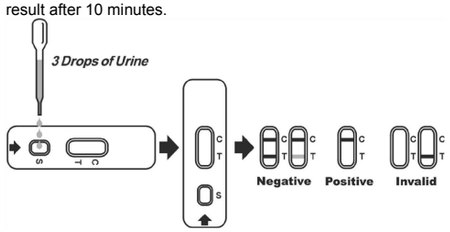
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test strip, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100μL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



Test Results

INTERPRETATION OF RESULTS

(Please refer to the illustration above)
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 whenever there is even a faint distinguishable
color line.
POSITIVE: One color line appears in the control region (C). 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 red 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.
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 One Step K2 Test Strip (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.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

BIBLIOGRAPHY

1. Auwarter V et. al. 'Spice' and other herbal blends: harmless incense or cannabinoid designer drugs? J. Mass Spectrom. 44: 832-837 (2009).
2. 2. U.S Drug Enforcement Administration (DEA). Drugs and Chemicals of Concern: JWH-073.(2009). http://www.deadiversion.usdoj.gov/drugs_concern/spice/spice_jwh073.html
3. 3. U.S. Drug Enforcement Administration (DEA). Drugs and Chemicals of Concern: JWH-018. (2009). http://www.deadiversion.usdoj.gov/drugs_concern/spice/spice_jwh018.htm

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2℃~30℃	Store between 2~30℃	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,LTD
Add:679#, East Yangguang Avenue, Dipu Town, Anji 313300, Zhejiang, China
Tel:+86-572-5226111
Fax: +86-572-5226222
Web site: www.orientgene.com

EC REP Wellkang Ltd t/a Wellkang Tech Consulting
Add:Suite B Harley Street,LONDON W1G 9QR,England,United Kingdom