# One Step K2 Drug of Abuse Test

*(Dip Card)*

*Package Insert for Single Drug Screen Test*

This Instruction Sheet is for testing of K2/Spice Synthetic Cannabinoid

A rapid, one step screening test for the qualitative detection of single drug and its metabolites in human urine.

**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 single drug and its metabolites in urine at the following cut-off concentration:

| Test | Calibrator | Cut-off |
|---|---|---|
| K2 Synthetic Cannabinoid | JWH-073/JWH-018 | 75ng/mL |

This assay provides only a preliminary qualitative test result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

## SUMMARY AND EXPLANATION OF THE TEST

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 75ng/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 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 2-30ºC (36-86ºF). 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. Do not uses after the expiration date.

## 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 2ºC-8ºC (36ºF-46ºF) for up to 48 hours. For prolonged storage, specimens may be frozen and stored below -20ºC. 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

## DIRECTIONS 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 results 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 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 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 Drug of Abuse Test 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. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Test does not distinguish between drugs of abuse and certain medications.
4. A positive test result may be obtained from certain foods or food supplements.

## REFERENCES

1. Auwarter V et. al. 'Spice' and other herbal blends: harmless incense or cannabinoid designer drugs? *J. Mass Spectrom.* 44: 832-837 (2009).
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. 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