Branan Medical Corporation

Fastect® II Synthetic Cannabinoid (K2) Dipstick Test

Catalog No. MF30

Intended Use
The Fastect® II K2 Dipstick Test is an in *vitro* screen test for the rapid detection of JWH-018 N-pentanoic acid metabolite at cut-off level of 10ng/mL and JWH-073 N-butanoic acid metabolite at cut-off level of 5ng/mL in human urine.

The Fastect® II K2 Dipstick Test provides visual qualitative results and is intended for forensic use only and is not for use in diagnostic procedures.

The Fastect® II K2 Dipstick Test provides only preliminary drug test results. For a quantitative result or to confirm a positive result obtained by the Fastect® II K2 Dipstick, a more specific alternative method must be used. Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) is the preferred confirmatory method.

Summary and Explanation
Synthetic cannabinoid is an herbal and chemical product which mimics the effects of cannabinoid. A large and complex variety of synthetic cannabinoids, most often cannabicyclohexanol, JWH-018, JWH-073, JWH-250, and HU-210 are used. They are the primary synthetic cannabinoid receptor agonists responsible for the euphoric and psychoactive effects that imitate marijuana. Chemically they are not similar to cannabinoid but the term "Synthetic Cannabinoids" is widely used to refer to them as they're cannabinoid-like in their activity. It is best known by the brand name K2 and Spice, both of which have largely become generic trademark use for refer to any synthetic cannabis product.

Test Principle
The Fastect® II K2 Dipstick test is based on the principle of the highly specific immunochemical reactions between antigens and antibodies, which are used for the analysis of specific substances in urine. The assay is based on a competitive immunoassay procedure in which immobilized drug conjugates compete with the drug(s) present in urine for limited antibody binding sites. The test device consists of individual test strips assembled into separate chambers of a plastic insert. On the membrane strip, a drug conjugate is pre-coated at a specific region known as the test region (T). A colored antibody-colloidal gold conjugate is coated onto a pad and placed at one end of the membrane strip. In the test procedure, The Fastect® II K2 dipstick test device is dipped into a urine sample. This allows the urine into contact with the sample pads of the Fastect® II dipstick test. The urine then migrates across the membrane by capillary action. If any drug is present in the urine, it competes with the drug conjugate, which is immobilized on the membrane for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibody binding sites and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. Therefore, the absence of a color band at a specific test region indicates a positive result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the specific test region of the membrane. The presence of a color band at a specific test region indicates a negative result for that particular test.

A control band with a different antigen/antibody reaction is added to the immuno-chromatographic membrane strip at the control region (C) to indicate that the test performed properly. This control band should always appear regardless of the presence of drug or metabolite.

Reagents
K2-protein conjugate is coated onto specific region on the membrane known as the “Test Region”.
The color conjugate pad for the test strip contains K2 antibody colloidal gold conjugate coated onto a fibrous pad.

Materials Provided
Each Fastect® II K2 Dipstick Test kit contains:
1. 1 Package Insert (Direction for use).
2. 50 Dipstick Tests. Each test device is packaged with a desiccant and sealed in a foil pouch.

Warnings and Precautions
- FOR FORENSIC USE ONLY
- The test device should remain in its original sealed pouch until ready for use.
- Discard the test device if package is ripped or torn.
- Handle all urine specimens as if potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

Product Storage
The Fastect® II K2 Dipstick Test should be stored at room temperature (15°–30°C) until the expiration date on the label. Do not open pouch until ready to perform the assay.

Specimen Collection and Handling
Fastect® II K2 Dipstick Test is formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Urine samples should be collected so that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing.

Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

Test Procedure
IMPORTANT: Donor sample (urine specimen) should be brought to room temperature (15°-30°C) prior to testing. Do not open pouch until ready to perform the assay.
1. Remove the test device from the sealed pouch by tearing at the notch.
2. Push the sleeve all the way up.
3. Dip the sample pad of the test device into the sample for at least 10 seconds. **Dip up to, but not beyond the tip of the arrows.**
4. Slide the sleeve down to the read indicator mark and lay the device on a level surface.
5. Once the control band (C) appears (in 5 minutes or less) results are ready to interpret. Read results at 5 minutes.

Interpreting Test Results
Negative: The presence of a colored band at the control region (C) and a colored band at a specific test region regardless of the intensity indicate a negative result.

Positive: The presence of a colored band at the control region (C) and the absence of a colored band at the test region indicate a positive result.

Invalid: No band appears at the control region (C). The test is inconclusive even if there is a band in the test region. If the test device does not produce a band at the control region, check testing procedures, samples, and/or control materials, and repeat the test using a new device.

Important: Samples with faint test bands at the test regions should be considered negative. The Fastect® II K2 Dipstick Test provides qualitative results for the presence of drug(s) at specified cut-off concentrations. It is recommended that samples with questionable test bands and positive results be confirmed with a more specific quantitative method (Liquid Chromatography/Mass Spectrometry/Mass Spectrometry).

Quality Control
Internal control: The Fastect® II K2 dipstick test has built-in internal procedural controls. The appearance of the control bands (C) is considered an internal procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed. Additionally, the background color should become clear and provide distinct test results. If the control bands (C) do not appear then the test is invalid. The test should be repeated using a new device.

External control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as with a urine specimen. When external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

Limitations of Procedure
- The assay is designed for use with human urine only.
- Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- There is a possibility that technical or procedural error as well other substances in certain food and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce either positive results, and Interference section for the list of components that do not interfere with test performance.
- If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain food and/or medication.
- If it is suspected that the sample may have been mislabeled a new specimen should be collected.
- If it is suspected that the sample may have been tampered, a new specimen should be collected.

Performance Characteristics

Precision

Drug-free normal urine was spiked with drug standard to various concentrations (-50%, -25%, +25% and +50%). For each concentration, a total of 30 tests were performed to validate the test performance around the cut-off concentration. The results for Fastect® II K2 Dipstick Test are summarized below:

Drug Test	Total # of Test / Conc.	Concentration							
		-50%		-25%		+25%		+50%	
		-	+	-	+	-	+	-	+
K2	30	30	0	28	2	5	25	1	29

Accuracy

The accuracy of the Fastect® II K2 Dipstick Test was evaluated with clinical urine samples. Twenty (20) negative urine samples were collected from volunteer donors and tested. Of the twenty negative urine samples tested, all were found negative by the Fastect® II K2 Dipstick Test. Additionally, twenty-three clinical urine samples previously analyzed by LC/MS/MS method with known concentration(s) of drug(s) values were blind labeled and evaluated. The results are summarized below:

Sample #	LC/MS/MS value		Fastect® II K2 Test
	JWH-073	JWH-018	
1	0.34	Neg.	Negative
2	Neg.	0.51	Negative
3	Neg.	0.67	Negative
4	0.28	1.7	Negative
5	0	1.94	Negative
6	0.33	2.8	Positive
7	0.32	1.18	Positive
8	0.39	4.7	Positive
9	0.52	10	Positive
10	0.6	10	Positive
11	0.85	12.2	Positive
12	0.43	16.8	Positive
13	0.71	17	Positive
14	0.48	19	Positive
15	2.5	20	Positive
16	1.73	22.8	Positive
17	0.93	56.1	Positive
18	2	56	Positive
19	2.16	70	Positive
20	5.8	76	Positive
21	6.6	>100	Positive
22	10	>100	Positive
23	11	>100	Positive

Specificity

The effect of pH and specific gravity of the specimen on the performance of the Fastect® II K2 test at ±50% cut-off levels were tested. Results obtained were acceptable and not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

The specificity study for the Fastect® II K2 Dipstick Test was evaluated by adding structurally related compounds to normal human urine. The results are expressed as the amount in ng/ml of the compound that was observed to produce a positive result.

Compound	ng/ml
JWH-018 N-pentanoic acid metabolite	10
JWH-018	250
JWH-018 N-(5-hydroxypentyl) metabolite	200
JWH-018 5 hydroxyindole metabolite	2500
JWH-018 6 hydroxyindole metabolite	1250
JWH-073-butanoic acid	5
JWH-073 – 6-hydroxyindole metabolite	2000
JWH-073 – 7-hydroxyindole metabolite	2000
JWH-250 N-(5-carboxypentyl) metabolite	800

Interference

Various drugs, drug metabolites, and other constituents commonly found in urine were evaluated for interferences and cross-reactivity. The following compounds were found not to cross-react with the Fastect® II K2 Dipstick Test device when tested at concentrations of 100µg/ml:

Acetaminophen
Acetylsalicylic acid (Aspirin)
d-Amphetamine
l-Amphetamine
Ampicillin
Atropine
Benzoylecgonine
Buprenorphine
Butalbital
Codeine
Cortisone
Hydrocortisone
Hydromorphone
Ketamine HCl
d,l-3,4-Methylenedioxymethamphetamine
Morphine
Oxazepam
Oxycodone
Penicillin-G
Phencyclidine
Phenobarbital
d-Pseudoephedrine
Secobarbital
11-nor-Δ8-THC-9-Carboxylic Acid
11-nor-Δ9-THC-9-Carboxylic Acid

Bibliography of Suggested Reading

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