PreScreen Plus

K3

One Step K3 Test Dip card (Urine)

Package Insert

This Instruction Sheet is for testing of AB-PINACA
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 K3 Test Dip card (Urine) is a lateral flow chromatographic immunoassay for the detection of *single drug and its metabolites* in human urine.

Test	Calibrator	Cut-off
K3	AB-PINACA	10 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

AB-PINACA is a compound that was first identified as a component of synthetic cannabis products in Japan in 2012.[1] It was originally developed by Pfizer in 2009 as an analgesic medication.[2][3] AB-PINACA acts as a potent agonist for the CB_1 receptor (K_i = 2.87 nM, EC_{50} = 1.2 nM) and CB_2 receptor (K_i = 0.88 nM, EC_{50} = 2.5 nM) and fully substitutes for Δ^9-THC in rat discrimination studies, while being 1.5x more potent.[4][5] There have been a number of reported cases of deaths and hospitalizations in relation to this synthetic cannabinoid.

Synthetic cannabis type "K3" is now also known as AB-PINACA and AB-FUBINACA.
Synthetic cannabis has nothing to do with natural cannabis. It is actually an active chemical and artificial substance. It is called "cannabis" because it mimics natural cannabis by acting on the same receptors of the organism, namely the CB1 and CB2 receptors.

Its chemical composition is completely different from natural cannabis, and as such, synthetic cannabis must be screened with a test specific to it, just like any other drug.
This test will detect the two main molecules of K3, AB-PINACA and AB-FUBINACA.
The One Step K3 Test Dip card yields a positive result when AB-PINACA in urine exceed 10ng/mL.

PRINCIPLE

The One Step AB-PINACA 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 Dip card 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 monodonal AB-PINACA antibody.

PRECAUTIONS

- For Forensic Use Only. Do not use after the expiration date.
- The test Dip card 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 Dip card 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 Dip card is stable through the expiration date printed on the sealed pouch. The test Dip card 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

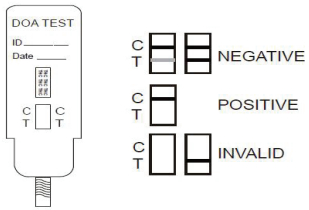
• Test device • Desiccants • Package insert • Urine cups

Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.
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 10-15 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.



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 K3 Test Dip card (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.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted by laboratory personnel using the One Step K3 Test Dip card and a commercially available rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by LC/MS. The following results were tabulated:

Method		LC/MS		Total Results
AB-PINACA Rapid Test Dip card	Results	Positive	Negative	
	Positive	35	0	35
	Negative	0	235	235
Total Results		35	235	270
% Agreement		>99%	>99%	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with AB-PINACA at the following concentrations: 0 ng/mL, 5 ng/mL, 7.5 ng/mL, 10 ng/mL, 12.5 ng/mL and 15 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

AB-PINACA Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0	30	30	0
5	-50%	30	30	0
7.5	-25%	30	29	1
10	Cutoff	30	17	13
12.5	+25%	30	2	28
15	+50%	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by The One Step K3 Test Dip card (Urine) at a read time of 5 minutes.

Compound	Concentration (ng/mL)
AB-PINACA	
AB-Pinaca	10
AB-PINACA 5-hydroxypentyl metabolite	10
AB-PINACA 4-hydroxypentyl metabolite	10
AB-FUPINACA	100

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

AB-PINACA conc.(ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
5	40	40 negative	>99%
15	40	40 positive	>99%
20	40	40 positive	>99%

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step K3 Test Dip card was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 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 K3 Test Dip card. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or AB-PINACA positive urine. The following compounds show no cross-reactivity when tested with The One Step K3 Test Dip card (Urine) at a concentration of 100 μg/mL.

Non Cross Reacting Compounds

4-Acetamidophenol	Butabarbital	Oyster calcium carbonate	JWH-018 5-Hydroxypentylmetabolite
1-Adamantanamine hydrochloride	Butalbital	Fexofenadine Hydrochloride	JWH-073 4-Hydroxybutyl metabolite
Chlorpheniramine maleate	Butylone HCl	Rabeprazole sodium	JWH-019 5-hydroxyhexylmetabolite
Caffeine	Clenbuterol HCl	Compound Paracetamol and Amantadine Hydrochloride Tablets	JWH-019 6-Hydroxyhexyl
Cafaclor	Clomipramine	Mosapride Citrate	Ethyl-β-D-glucuronide
Methyltestosteronetablets	Clonazepam	Dexamethasone acetate	Ethyl-β-D-glucuronide-D5
Ibuprofen	Clorazepate Dipotassium	Desloratadine	Ecgonine
Ranitidine	Cyclobenzaprine Hydrochloride	Vitamin U belladonna aluminum	Ecgonine methylester
Loratadine	Delorazepan	Metronidazole	(1R,2S)-(-)-Ephedrine
Cefadroxil	Desipramine	(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	β-Phenylethylamine
Nordiazepam-D5	Dihydrocodeine HCl	Trimethobenzamide	Fentanyl
Telmisartan	Diphenhydramine HCl	Chloroquine	Nicotine
Citicoline Sodium	Doxepin HCl	p-Hydroxymethamphetamine	6-acetylmorphine
Gatifloxacin	Doxylamine	Cocaethylene	Nalorphine
Indapamide	Ethylmorphine	Cocaine HCl	Normorphine
Amoxicillin	Ethylone HCl	Codeine	Norcodeine
Cefixime	Flunitrazepam	Heroin	Delta-9-Tetrahydrocannabinol
Buspirone HCl	Hydrocodone	Bromazepam	(-)-11-nor-9-carboxy-delta9-THC
Diclofenac sodium	Hydromorphone	Chlordiazepoxide HCL	11-Hydroxy-Δ9-Tetrahydrocannabinol
Ciprofloxacin hydrochloride	Imipramine	Clobazam	Alphenal （Phenobarbital）
Ephedrine Hydrochloride	Levorphanol	Desalkylflurazepam	LAAM HCl
Papaverine Hydrochloride	Lorazepam glucuronide	Diazepam	Cotinine
Triazolam	Lorazepam-D4	Estazolam	Compound Tropicamide Eye Drops
Promethazine Hydrochloride	Midazolam	RS-Lorazepam glucuronide	Brompheniramine
Bupropion Hydrochloride	N-Desmethyl-cis-tramadol	Norchlordiazepoxide	Flephedrone(4-fluoromethcathinone)
Scopolamine Hydrobromide	Nitrazepam	Nordiazepam	Methylone
Procaine Hydrochloride	Normeperidine-D4	Temazepam	Pyrovalerone
Tramadol Hydrochloride	Norpropoxyphene	Amobarbital	Naphyrone
Morphine	O-desmethyl-tramadol	Buprenorphine-3-D-Glucuronide	Mephedrone
Codeine Phosphate	Oxymorphone-D3	Norbuprenorphine	Methedrone
Diacetyl Morphine Hydrochloride	Pentobarbital	Oxymorphone	Zomepirac
Naloxone hydrochloride	R(+)-Methcathinone	EMDP	JWH-210 4-Hydroxypentyl metabolite
γ-aminobutyric acid	S(-)-Methcathinone	Disopyramide	JWH-122 4-Hydroxypentyl metabolite-D5
Methadone	Trimipramine	D-Amphetamine	JWH-018
Buprenorphine Hydrochloride	Zolpidem-D6	Phentermine	JWH-250 5-Hydroxypentyl metabolite
Naltrexone	Zolpidem-D7	(+/-)-4-Hydroxyamphetamine HCL	Spice Cannabinoid Mix
Metoprolol	Zopiclone	D，L-Amphetamine	JWH-250 4-Hydroxypentyl metabolite
Topiramate	Desloratadine Citrate Disodium	(+/-)-Methylenedioxyamphetamine(MDA)	Spice Cannabinoid Mix 2
Trazodone Hydrochloride	Compound Glycyrrhizin Capsules	l-Methamphetamine	JWH-073 (3-Hydroxybutyl) metabolite
Sertraline Hydrochlloride	Cefuroxime Axetil	Doxepine	JWH-073
(±) Lorazepam	Cefaclor Dispersible Tablets	Maprotiline	JWH-122 4-Hydroxypentyl
Alpha-Hydroxyalprazolam	Azithromycin	JWH-018 5-Pentanoic acid metabolite	JWH-122 5-Hydroxypentyl
Alprazolam	Dextromethorphan Hydrobromide	JWH-073 4-butanoic acid metabolite	JWH-210 5-Hydroxypentyl
Amitriptyline HCl	Aspirin	JWH-018 4-Hydroxypentyl metabolite	Spice Cannabinoid Mix 3

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