Multi-Drug Rapid Test Panel (AB-PINACA /UR-144/ JWH)(Urine)
Package Insert

A rapid test for the qualitative detection of AB-PINACA /UR-144/ JWH in human urine.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Multi-Drug Rapid Test Panel is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cutoff(ng/ml)
AB-PINACA	AB-PINACA	10
UR-144	UR-144 5-Pentanoic acid	25
JWH	JWH-18/JWH-73	50

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 indicated.

【SUMMARY】

JWH

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 72 hours after smoking (depending on usage/dosage).

As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclo hexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

UR-144

UR-144 is a synthetic cannabinoid receptor agonist (SCRA) and has affinity for CB1 and CB2 receptors. It has a high selectivity for the CB2-receptors.

UR-144 is a psychoactive substance and has effects similar to delta-9-tetrahydrocannabinol (THC), though slightly less potent than THC.[5] UR-144 has been detected in herbal products marketed under a variety of names.

In mice, UR-144 is moderately potent in reducing in a time- and dose-dependent manner the locomotor activity (ID50-value 7.8 mg/kg), induces an anti-nociceptive effect, and decreases rectal temperature and ring immobility with potencies several-fold greater than THC. In mice, UR-144 substituted for THC in a THC discrimination study (ED50-value 7.1 to 7.4 µmol/kg intra-peritoneal), an effect antagonized by rimonabant.[6]

AB-PINACA

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] AB-PINACA acts as a potent agonist for the CB1 receptor (Ki = 2.87 nM, EC50 = 1.2 nM) and CB2 receptor (Ki = 0.88 nM, EC50 = 2.5 nM) and fully substitutes for Δ9-THC in rat discrimination studies, while being 1.5x more potent.[3, 4]

【PRINCIPLE】

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 region of the specific drug dipstick. 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 region. A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】

- For medical and other professional in vitro diagnostic use only. Do not uses after the expiration date.
- The test 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 should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test 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 Panels
- Package Insert

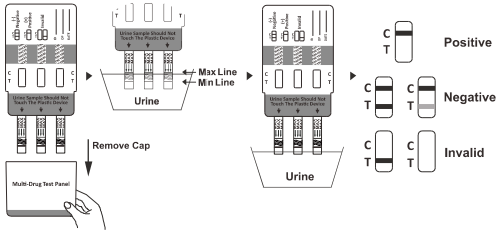
Materials Required But Not Provided

- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least **10 to 15 seconds.** Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The drug strip result should be read at **5 minutes**. Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

【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 and correct procedural technique.

Control standards are not supplied with this Test Panel; however it is recommended that positive and negative controls be tested as good laboratory testing practices to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. Multi-Drug Rapid Test Panel (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrophotometry (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.

【EXPECTED VALUES】

This negative result indicates that the drug concentration is below the designated cut-off levels. Positive result means the concentration of drug is above the designated cut-off levels.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using The AB-PINACA/UR-144/JWH Rapid Test Panel (Urine) and GC/MS. Testing was performed on clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		% agreement with GC/MS
Multi-Drug Rapid Test Panel		Positive	Negative	
AB-PINACA 10	Positive	23	2	92.0%
	Negative	2	68	97.1%
UR-144 25	Positive	34	1	97.1%
	Negative	1	62	98.4%
JWH 50	Positive	78	3	97.5%
	Negative	2	167	98.2%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

Drug Concentration Cut-off Range	AB-PINACA 10ng/mL		UR-144 25ng/mL		JWH 50ng/mL	
	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0
-25% Cut-off	25	5	28	2	27	3
Cut-off	15	15	15	15	15	15
+25% Cut-off	4	26	3	27	3	27
+50% Cut-off	0	30	0	30	0	30
+300%Cut-off	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drug Rapid Test Panel at 5 minutes.

Analytes	Conc.(ng/mL)	Analytes	Conc.(ng/mL)
AB-PINACA			
AB-PINACA	10	UR-144 4-hydroxypentyl	10,000
AB-PINACA 5-Pentanoic	10	APINACA 5-hydroxypentyl	10,000
AB-PINACA 5-hydroxypentyl	10	ADB-PINACA N-(5-hydroxypentyl)	30
AB-FUBINACA	10	ADB-PINACA Pentanoic Acid	10
AB-PINACA 4-hydroxypentyl	10,000	5-fluoro AB-PINACA N-(4-hydroxypentyl)	30
UR-144 5-Pentanoic	5,000	5-fluoro AB-PINACA	25
UR-144 5-hydroxypentyl	10,000	AB-CHMINACA	>10,000
AMB-FUBINACA	100	UR-144 N-S chloro pentyl	10,000
EMB-FUBINACA	100	5F-APINACA	10,000
UR-144			
UR-144 5-Pentanoic acid	25	UR-144 4-hydroxypentyl	10,000
UR-144 5-hydroxypentyl	5000	XLR-11 4-hydroxypentyl	2,000
5-fluoro AB-Pinaca N-(4-hydroxypentyl)	10,000	ADB-PINAC N-(4-hydroxypentyl)	>10,000
AB-PINACA 4-hydroxypentyl	>10,000		
JWH			
JWH-018 5-Pentanoic acid	50	JWH-019 5-hydroxypentyl	10,000
JWH-073 4-Butanoic acid	50	JWH-019	10,000
JWH-073 N-(3-hydroxypentyl)	8,000	JWH-122 N-(5-hydroxypentyl)	5,000
JWH-018 N-(4-hydroxypentyl)	10,000	JWH-398 N-Pentanoic acid	500
MAM2201 N-Pentanoic	300	JWH-200 6-hydroxyindole	15,000
JWH-122 N-(4-hydroxypentyl)	2,000	JWH-210 N-Pentanoic acid	1,000
JWH-018 N-Pentanoic	150	RCS4 N-5-Carboxypentyl	1,000
JWH-073 N-(2-hydroxybutyl)	5,000	JWH-073 4-Hydroxybutyl	500
JWH-018 N-(5-hydroxypentyl)	5,000	JWH-073 4-Pentanoic	10,000
JWH-018 4-Hydroxypentyl	400	JWH-018 5-Hydroxypentyl	500

Precision

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical card of coded specimens, containing drugs at concentrations of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AB-PINACA

AB-PINACA	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	10	0	10	0	10	0
7.5	10	8	2	8	2	9	1
12.5	10	2	8	3	7	1	9
15	10	0	10	0	10	0	10

UR-144

UR-144 5-Pentanoic	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	9	1	8	2	9	1
31.25	10	1	9	2	8	2	8
37.5	10	0	10	0	10	0	10

JWH

JWH-018 5-Pentanoic acid	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
25	10	10	0	10	0	10	0
37.5	10	8	2	8	2	9	1
62.5	10	1	9	2	8	2	8
75	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test Panel was tested in duplicate using fifteen 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 a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the Multi-Drug Rapid Test Panel. 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 Marijuana positive urine. The following compounds show no cross-reactivity when tested with The Multi-Drug Rapid Test Panel (Urine) at a concentration of 100μg/ml.

Non Cross-Reacting Compounds

4-Acetamidophenol	Deoxycorticosterone	(+) 3,4-Methylenedioxy-	Prednisolone
Acetophenetidin	Dextromethorphan	amphetamine	Prednisone
N-Acetylprocainamide	Diazepam	(+) 3,4-Methylenedioxy-	Procaine
Acetylsalicylic acid	Diclofenac	methamphetamine	Promazine
Aminopyrine	Diflunisal	Methylphenidate	Promethazine
Amitryptyline	Digoxin	Methyprylon	D,L-Propanolol
Amobarbital	Diphenhydramine	Morphine-3-	D-Propoxyphene
Amoxicillin	Doxylamine	β–D-glucuronide	D-Pseudoephedrine
Ampicillin	Ecgonine hydrochloride	Nalidixic acid	Quinidine
L-Ascorbic acid	Ecgonine methylester	Nalorphine	Quinine
D,L-Amphetamine	(-)-ψ-Ephedrine	Naloxone	Ranitidine
L-Amphetamine	Erythromycin	Naltrexone	Salicylic acid
Apomorphine	β-Estradiol	Naproxen	Secobarbital
Aspartame	Estrone-3-sulfate	Niacinamide	Serotonin (5-
Atropine	Ethyl-p-aminobenzoate	Nifedipine	Hydroxytyramine)
Benzilic acid	Fenoprofen	Norcodein	Sulfamethazine
Benzoic acid	Furosemide	Norethindrone	Sulindac
Benzoylecgonine	Gentisic acid	D-Norpropoxyphene	Temazepam
Benzphetamine	Hemoglobin	Noscapine	Tetracycline
Bilirubin	Hydralazine	D,L-Octopamine	Tetrahydrocortisone,
(±)-Brompheniramine	Hydrochlorothiazide	Oxalic acid	3-Acetate
Caffeine	Hydrocodone	Oxazepam	Tetrahydrocortisone
Cannabidiol	Hydrocortisone	Oxolinic acid	3 (β-D-glucuronide)
Chloralhydrate	O-Hydroxyhippuric acid	Oxycodone	Tetrahydrozoline
Chloramphenicol	3-Hydroxytyramine	Oxymetazoline	Thebaine
Chlordiazepoxide	Ibuprofen	p-Hydroxy-	Thiamine
Chlorothiazide	Imipramine	methamphetamine	Thioridazine
(±) Chlorpheniramine	Iproniazid	Papaverine	D, L-Thyroxine
Chlorpromazine	(±) - Isoproterenol	Penicillin-G	Tolbutamine
Chlorquine	Isoxsuprine	Pentazocine	Triamterene
Cholesterol	Ketamine	Pentobarbital	Trifluoperazine
Clomipramine	Ketoprofen	Perphenazine	Trimethoprim
Clonidine	Labetalol	Phencyclidine	Trimipramine
Cocaine hydrochloride	Levorphanol	Phenelzine	Tryptamine
Codeine	Loperamide	Phenobarbital	D, L-Tryptophan
Cortisone	Maprotiline	Phentermine	Tyramine
(-) Cotinine	Meprobamate	L-Phenylephrine	D, L-Tyrosine
Creatinine	Methadone	β-Phenylethylamine	Uric acid
Methoxyphenamine	Phenylpropanolamine	Verapamil	Zomepirac

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Index of Symbols

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

Number: 145910300
Effective date: 2018-09-29