



UR-144 Rapid Test Cassette (Urine) Package Insert

REF DUR144-C11	English
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A rapid test for the qualitative detection of UR-144 metabolite in human urine.
For professional *in vitro* diagnostic use only.

【INTENDED USE】

The UR-144 Rapid Test Cassette is a rapid chromatographic immunoassay for the detection of UR-144 5-Pentanoic acid metabolite in human urine at the cut-off concentration of 25 ng/mL. This test will detect other compounds, please refer to Analytical Specificity table in this package insert.

This assay provides only a qualitative, 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】

UR-144 5-Pentanoic acid metabolite, a primary urinary metabolite of UR-144, a synthetic cannabinoid found in many blends of the herbal mixture Spice also known as K2, Genie, or Demon, which has been detected in many 'legal highs', seized from the global drug market since the beginning of 2012.

(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) is a synthetic cannabinoid receptor agonist (SCRA) that binds to and activates CB1 and CB2 receptors and the currently available data also suggest that UR-144 shows selectivity towards the CB2 receptor. Although there is an increasing indication that some SCRA's have been associated with dependence producing features, studies related to UR-144 specifically are not available.

Abuse potential: Clinical studies in humans could not be identified. Pharmacological investigations (in vitro and in vivo) confirmed that UR-144 shares similarities with Δ9-THC and other cannabinoid receptor agonists in its mechanisms of action, which was in alignment with the documented history of its use over several years since it emerged as a 'research chemical' around 2012. Most commonly, this substance is encountered in the form of smokable 'herbal mixtures' although other forms have also been identified¹.

The UR-144 Rapid Test Cassette is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of UR-144 5-Pentanoic acid metabolite in urine. The UR-144 Rapid Test Cassette yields a positive result when UR-144 5-Pentanoic acid metabolite in urine reaches 25 ng/mL.

【PRINCIPLE】

The UR-144 Rapid Test Cassette is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. UR144 5-Pentanoic acid metabolite, if present in the urine specimen below 25 ng/mL, will not saturate the binding sites of the antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized UR-144 conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the UR-144 5-Pentanoic acid metabolite level is at or above 25ng/mL because it will saturate all the binding sites of anti-UR-144 antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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 mouse monoclonal anti-UR-144 antibody-coupled particles and UR-144-protein conjugate. A rabbit antibody is employed in the control line system.

【PRECAUTIONS】

- For medical and other professional *in vitro* diagnostic use only. Do not use 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 in the sealed pouch either 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 assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS PROVIDED】

Material provided

- Test cassettes
- Droppers

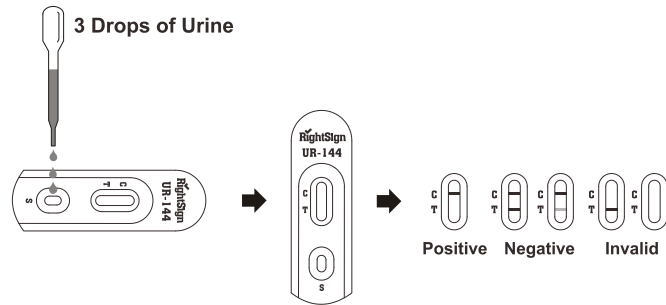
Materials required but not provided

- Specimen collection container
- Timer

- Package insert

【DIRECTIONS FOR USE】

- Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it within one hour.
- Place the cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine (approximately 120μl)** to the specimen well of the cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- Wait for the color line(s) to appear. **The result should be read at 5 minutes.** It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



【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 should be in the test region (T). This negative result indicates that the UR-144 5-Pentanoic acid metabolite concentration is below the detectable cut-off level.

***NOTE:** The shade of color in the test region (T) may vary, but it should be considered negative whenever there is even a faint 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 UR-144 5-Pentanoic acid metabolite concentration is above the detectable cutoff 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 with a new test. If the problem persists, discontinue using the test immediately and contact your local distributor.

【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.

Control standards are not supplied with this test; 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】

- The UR-144 Rapid Test Cassette 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^{2,3}.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the UR-144 5-Pentanoic acid metabolite concentration is below the detectable level of 25 ng/mL. Positive result means the concentration of UR-144 5-Pentanoic acid metabolite is above the level of 25 ng/mL. The UR-144 Rapid Test Cassette has a sensitivity of 25 ng/mL.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using The UR-144 Rapid Test Cassette and GC/MS at the cut-off of 25ng/mL. Drug free urine samples collected from presumed non-user volunteers, the positive urine samples were spiked with UR-144 calibrator. Testing was performed on 100 specimens. The following results were tabulated:

Method	GC/MS		Total Results
	Positive	Negative	
UR-144 Rapid Test	Results		
	Positive	48	49
	Negative	2	51
Total Results	50	50	100
% Agreement with GC/MS	96%	98%	97%

Analytical Sensitivity

A drug-free urine pool was spiked with UR-144 5-Pentanoic acid metabolite at the following concentrations: 0ng/mL, 12.5ng/mL, 18.75ng/mL, 25ng/mL, 31.25ng/mL, 37.5ng/mL and 75ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

UR-144 Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
12.5	-50%	30	30	0
18.75	-25%	30	12	18
25	Cutoff	30	3	27
31.25	+25%	30	0	30
37.5	+50%	30	0	30
75	3X	30	0	30

Precision

A study was conducted at 3 labs by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision or by in-house personnel at the manufacturing site. An identical panel of coded specimens containing, according to GC/MS, no UR-144 5-Pentanoic acid metabolite, 25% UR-144 5-Pentanoic acid metabolite above and below the cut-off and 50% UR-144 5-Pentanoic acid metabolite above and below the 25ng/mL cut-off was provided to each site. The results are given below:

UR-144 5-Pentanoic acid metabolite Concentration (ng/mL)	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	10	0	9	1	9	1
31.25	10	0	10	1	9	0	10
37.5	10	0	10	0	10	0	10

Analytical Specificity

The following table lists compounds that are positively detected in urine by The UR-144 Rapid Test Cassette at 5 minutes.

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
UR144 5-Pentanoic acid metabolite	25	UR144 5-Hydroxypentyl metabolite	1,000
UR-144	10,000	AB-Pinaca Pentanoic acid metabolite	>100,000

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 12.5 ng/mL and 37.5 ng/mL of UR-144 5-Pentanoic acid metabolite. The UR-144 Rapid Test Cassette was tested in duplicate using the fifteen neat and spiked urine specimens. 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 UR-144 5-Pentanoic acid metabolite to 12.5ng/mL and 37.5ng/mL. The spiked, pH-adjusted urine was tested with The UR-144 Rapid Test Cassette in duplicate. 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 UR-144 5-Pentanoic acid metabolite. The following compounds show no cross-reactivity when tested with The UR-144 Rapid Test Cassette at a concentration of 100μg/mL.

Non-Cross-Reacting Compounds

(-) Epinephrine	D, L- Octopamine	Labetalol	Phentermine
(+/-) Epinephrine	D, L-Tryptophan	L-Amphetamine	p-Hydroxymethamphetamine
(+/-) Brompheniramine	D, L-Tyrosine	Lidocaine	Prednisolone
(+/-)-Chlorpheniramine	Deoxycorticosterone	Lindane	Prednisone
(+/-)-Phenylpropanolamine	Dextromethorphan	L-Methamphetamine	Procaine
MDA	Diclofenac	Loperamide	Promazine
(LR, 2S) - (-)-Ephedrine	Dicyclomine	L-Phenylephrine	Promethazine
3-Hydroxytyramine	Diffunisal	L-Thyroxine	Quinacrine
4-Acetamidophenol	Digoxin	Maprotiline	Quinidine
4-Dimethylaminoantipyrine	Diphenhydramine	MDMA	Quinine
5,5-Diphenylhydantoin	Disopyramide	Meperidine	R (-) Deprenyl
Acetone	D-Methamphetamine	Methadone	Ranitidine
Acetophenetidin	d-Norpropoxyphene	Methoxyphenamine	Riboflavin
Acetylsalicylic acid	Doxylamine	Motoprolol	S- (+)-Chlorpheniramine maleate salt
Albumin	d-Propoxyphene	Morphine sulfate	Salicylic acid
Amitriptyline hydrochloride	Ecgonine	Morphine-3-β-D-Glucuronide	Secobarbital
Amobarbital	Ecgonine methyl ester	Nalidixic acid	Serotonin(5-Hydroxytryptamine)
Amoxapine	Efavirenz	Nalorphine	Sodium chloride
Amoxicillin	Ephedrine	Naloxone	Sulfamethazine
Ampicillin	Erythromycin	Naltrexone	Sulindac

Apomorphine	Estrone-3-Sulfate	Nimesulide	Temazepam
Ascorbic acid	Ethanol (Ethyl alcohol)	Norcodeine	Tetracycline
Aspartame	Ethyl-p-aminobenzoate (Benzocaine)	Norethindrone	Tetrahydrozoline
Atropine	Etodolac	Normorphine	Thebaine
Benzilic acid	Famprofazone	Noscapine	Theophylline
Benzoic acid	Fenoprofen	O-Hydroxyhippuric acid	Thiamine
Bilirubin	Fluoxetine Hydrochloride	Orphenadrine	Thiordazine
Buspirone	Furosemide	Oxalic acid	Tolbutamide
Caffeine	Gentisic acid	Oxazepam	Trans-2-Phenylcyclopropylamine
Cannabidiol	Guaiacol Glyceryl Ether	Oxolinic acid	Trazodone
Cannabinol	Guaiacol Glyceryl Ether carbamate	Oxycodone	Triamterene
Chloramphenicol	Hemoglobin	Oxymetazoline	Trifluoperazine
Chloroquine	Hydralazine	Oxymorphone	Trimethobenzamide
Chlorpromazine	Hydrochlorothiazide	Papaverine	Trimethoprim
Chlorprothixene	Hydrocodone	Pemoline	Trimipramine
Cholesterol	Hydrocortisone	Penicillin	Tryptamine
Cimetidine	Hydroxyzine	Pentazocine	Tyramine
Clomipramine	Ibuprofen	Perphenazine	Uric acid
Clonidine	Imipramine	Phencyclidine	Verapamil
Cocaine	Isoproterenol hydrochloride	Phenelzine	Zomepirac
Cortisone	Isoxsuprine	Pheniramine	α -Naphthaleneacetic Acid
Creatinine	Kanamycin	Phenobarbital	β-Estradiol
Phenobarbital	Ketamine	Phenothiazine	β-Phenylethylamine
Phenothiazine	Ketoprofen		

【BIBLIOGRAPHY】

- Expert Committee on Drug Dependence Thirty-ninth Meeting, Expert Peer Review No.1, Agenda Item 4.11: UR-144, Geneva, 6-10 November 2017.
- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
- Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Index of Symbols			
	Consult Instruction for use		Tests per kit
	For in vitro diagnostic use only		Use by
	Store between 2-30°C		Lot Number
	Do not use if package is damaged		
			Authorized Representative
			Do not reuse
			Catalog #



Hangzhou Biotest Biotech Co., Ltd.
 17#, Futai Road, Zhongtai Street,
 Yuhang District, Hangzhou, P. R. China





Shanghai International Holding Corp. GmbH (Europe)
 Effestrasse 80,
 20537 Hamburg, Germany

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