

# ALL TEST™ Multi-Drug X(2-15) Rapid Test Cassette (Hair) Package Insert

A rapid test to qualitative detection any combination of the following drugs in human hair: COT/MET/MOP/OPI/COC/6-MAM/KET/BAR/BUP/BZO/OXY/PCP/MDMA/AMP/K2/ABP For medical and other professional *in vitro* diagnostic use only.

## 【INTENDED USE】

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

Test	Calibrator	Cutoff(ng/mg)
Cotinine (COT)	Cotinine	0.2
Methamphetamine (MET)	d-Methamphetamine	0.2
Morphine/Opiate (MOP/OPI)	Morphine	0.2
Cocaine (COC)	Cocaine	0.5
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	0.2
Ketamine (KET)	Ketamine	0.2
Barbiturates (BAR)	Secobarbital	0.2
Buprenorphine (BUP)	Buprenorphine	0.2
Benzodiazepines (BZO)	Oxazepam	0.2
Oxycodone (OXY)	Oxycodone	0.2
Phencyclidine (PCP)	Phencyclidine	0.2
Methylenedioxyamphetamine (MDMA)	d,l-Methylenedioxyamphetamine	0.2
Amphetamine (AMP)	d-Amphetamine	0.2
Synthetic Marijuana (K2)	JWH-018 5-Pentanoic acid, JWH-073 4-butanoic acid	0.2
AB-PINACA (ABP)	AB-PINACA	0.2

This assay provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.<sup>1</sup> 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.<sup>2,5</sup>

## 【SUMMARY】

Hair detection has unique advantages in the field of drug testing.<sup>6,7</sup> Hair can provide long-term medication information that is not available in other biological samples such as blood and urine.<sup>8</sup> Hair samples are relatively easy to take, easy to carry, and easy to store for long periods of time. The slow metabolism of drugs in hair can persist for a long time, and these factors provide better conditions for drug analysis.

## 【PRINCIPLE】

During testing, the lysate decomposes keratin, the main component of hair, with lysate releasing drug molecules to be tested. Hair lysate migrates by capillary action. A drug, if present in the hair lysate 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 test. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not appear in the test region.

A drug-positive hair lysate specimen will not generate a colored line in the specific test region of the test because of drug competition, while a drug-negative hair lysate 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 in 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 (or anti-drug rabbit polyclonal antibody) and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies (or goat anti-mouse IgG monoclonal) and rabbit IgG (or mouse IgG).

## 【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 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.

Powder can be stored at 2-30°C for up to 18 months prior to testing. However it is enzyme-based reagent that works best when stored at 2-8°C. Therefore, even though the kit is stable up to 30°C, storage at 2-8°C range is advised for enhanced performances of the Powder.

## 【SPECIMEN COLLECTION AND PREPARATION】

### Hair Assay

The hair specimen must be collected from the center of the head and close to the root of the hair, in a clean and dry container.

## 【MATERIALS】

- Test Cassettes
- Package Insert
- Collection Card
- Buffer 1
- Specimen Collection Tubes with Powder
- Buffer 2
- Droppers

### Materials Provided

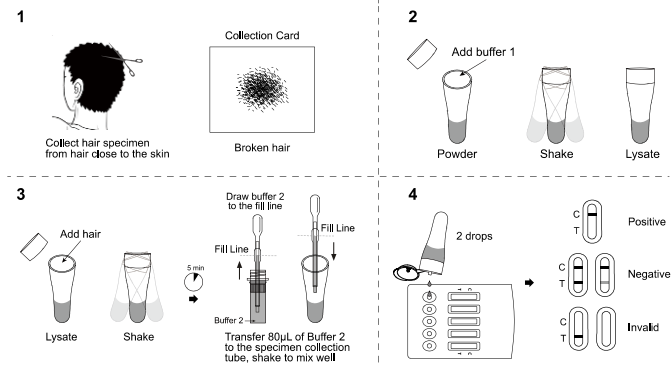
- Specimen Collection Containers
- Timer
- Scissors

### Materials Required But Not Provided

## 【DIRECTIONS FOR USE】

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

- Collect hair specimen from hair close to the skin and cut hair of no longer than 3 cm in length and not less than 100 mg. Cut the collected hair into small pieces.
- Add the Buffer 1 to the Specimen Collection Tube with Powder and shake it evenly to prepare the lysate.
- Add the hair sample to the prepared hair lysate; tighten the cap onto the specimen collection tube, then shake the tube to mix the specimen and the lysate. Leave the tube alone for 5 minutes.
- Draw the 80 µL of Buffer 2 to the fill line and then transfer to the specimen collection tube, shake to mix well.
- Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface. Open the cap of the specimen collection tube and transfer 2 full drops of specimen (approx. 80 µL) to each of the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
- Wait for the colored line(s) to appear. Read results 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 another colored line appears in the test regions (T). This negative result means that the concentrations of the target analyte in the hair are below the designated cut-off levels.

**\*NOTE:** The shade of the colored line(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 regions (T). The positive result means that the target analyte concentration in the hair sample is greater than the designated cut-off.

**INVALID:** Control line fails to appear. 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. If the result is still invalid, contact your manufacturer.

## 【QUALITY CONTROL】

A procedural control is included in the test. A colored 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; 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】

- Multi-Drug Rapid Test Cassette (Hair) 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.
- It is possible that technical or procedural errors, as well as other interfering substances in the hair specimen may cause erroneous results.
- Adulterants, such as bleach in hair specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another hair specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in hair.
- A negative result may not necessarily indicate drug-free hair. 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.

## 【PERFORMANCE CHARACTERISTICS】

### Accuracy

#### % Agreement with GC/MS

	COT	MET	MOP/OPI	COC	6-MAM	KET	BAR
Positive Agreement	90.0%	90.3%	90.9%	90.9%	91.9%	91.2%	91.4%
Negative Agreement	91.9%	91.5%	91.7%	92.2%	92.3%	92.4%	92.3%
Total Results	91.3%	91.3%	91.5%	91.8%	92.2%	92.0%	92.0%

	BUP	BZO	OXY	PCP	MDMA	AMP	K2	ABP
Positive Agreement	91.7%	92.1%	91.9%	92.3%	91.9%	92.5%	91.2%	91.4%
Negative Agreement	92.2%	92.3%	92.5%	91.9%	92.4%	92.3%	92.4%	92.3%
Total Results	92.0%	92.2%	92.3%	92.1%	92.2%	92.4%	92.0%	92.0%

### Analytical Sensitivity

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

Drug Concentration Cut-off Range	COT		MET		MOP/OPI		COC		6-MAM		KET		BAR	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	25	5	27	3	26	4	26	4	26	4	26	4	27	3
Cut-off	15	15	15	15	15	15	15	15	15	15	15	15	15	15
+25% Cut-off	4	26	3	27	3	27	3	27	3	27	3	27	4	26
+50% Cut-off	0	30	0	0	30	0	30	0	30	0	30	0	30	0
+300% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	BUP		BZO		OXY		PCP		MDMA		AMP		K2		ABP	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	26	4	27	3	26	4	26	4	26	4	26	4	27	3	27	3
Cut-off	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15	15
+25% Cut-off	4	26	3	27	3	27	3	27	3	27	3	27	4	26	4	26
+50% Cut-off	0	30	0	0	30	0	30	0	30	0	30	0	30	0	30	0
+300% Cut-off	0	30	0	0	30	0	30	0	30	0	30	0	30	0	30	0

### Precision

A study was conducted at three hospitals by untrained users 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 negative, ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results gained ≥75% accuracy in ± 25% cut-off level specimen and 100% accuracy in negative and ± 50% cut-off level specimen.

### Analytical Specificity

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

Analytes	Conc.(ng/mg)	Analytes	Conc.(ng/mg)
<b>COT</b>			
(-)-Cotinine	0.2	(-)-Nicotine	5
<b>MET</b>			
$\rho$ -Hydroxymethamphetamine	5	( $\pm$ )-3,4-Methylenedioxy methamphetamine	2.5
D-Methamphetamine	0.2		
L-Methamphetamine	4	Mephentermine	10
<b>MOP/OPI</b>			
6-Monoacetylmorphine	0.2	Morphine	0.2
Codeine	0.2	Pholcodine	0.2
Dihydrocodeine	0.6	Thebaine	20
Norcodeine	4	Morphine-3- $\beta$ -D-Glucuronide	0.6
Normorphone	35	Ethylmorphine	4
<b>COC</b>			
Cocaine	0.5	Benzoylcegonine	0.5
Cocathylene	13.5	Ecgonine	20
<b>6-MAM</b>			
6-Monoacetylmorphine	0.2		
<b>KET</b>			
Ketamine	0.2	Benzphetamine	5
Levorphanol tartrate	0.5	Phenytin	60
Tetrahydrozoline	30	o-Desmethyl-cis-tramadol	100
Pentazocine	4	Nalbuphine HCL	60
Promethazine Hydrochloride	>100	Morphine Hydrochloride	>100
paliperidone	>100		
<b>BAR</b>			
Secobarbital	0.2	Butalbital	1.4
Barbital	0.6	Amobarbital	1
<b>BUP</b>			
Buprenorphine	0.2	Norbuprenorphine	1
Buprenorphine 3-D-Glucuronide	1	Norbuprenorphine 3-D-Glucuronide	2
<b>BZO</b>			
Alprazolam	0.2	Clonazepam	6
Clobazam	0.2	Nitrazepam	0.2
Triazolam	2	Oxazepam	0.2
Flunitrazepam	0.8	Diazepam	0.2
( $\pm$ ) Lorazepam	2	Estazolam	4
<b>OXY</b>			
Oxycodone	0.2	Oxymorphone	0.6
<b>PCP</b>			
Phencyclidine	0.2		
<b>MDMA</b>			
d,l-Methylenedioxyamphetamine	0.2	( $\pm$ ) 3,4-Methylenedioxyamphetamine HCl	1.2
( $\pm$ ) 3,4-Methylenedioxy methamphetamine HCl	0.2	3,4-Methylenedioxyethyl-amphetamine	0.2
<b>AMP</b>			
d-Amphetamine	0.2	( $\pm$ ) 3,4-Methylenedioxy amphetamine	0.2
Phentermine	0.7		
<b>K2</b>			
JWH-018 5-Pentanoic acid	0.2	JWH-073 4-butanoic acid	0.2
JWH-018 4-Hydroxypentyl	1.6	JWH-018 5-Hydroxypentyl	2
JWH-073 4-Hydroxybutyl	2		
<b>ABP</b>			
AB-PINACA	0.2	UR-144 4-hydroxypentyl	>100
AB-PINACA 5-Pentanoic	0.2	APINACA 5-hydroxypentyl	>100
AB-PINACA 5-hydroxypentyl	0.2	ADB-PINACA N-(5-hydroxypentyl)	0.6
AB-FUBINACA	0.2	ADB-PINACA Pentanoic Acid	0.2
AB-PINACA 4-hydroxypentyl	>100	5-fluoro AB-PINACA N-(4-hydroxypentyl)	0.6
UR-144 5-Pentanoic	>100	5-fluoro AB-PINACA	0.5
UR-144 5-hydroxypentyl	>100		

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free hair or drug positive hair containing above related calibrator substances. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Cassette (Hair) at a concentration of 1000ng/mg.












### Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Zomepirac	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labeltalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diffunisal	Isoxsuprine	Sulfamethazine
l-Ascorbic acid	Digoxin	d,l-Propranolol	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone
Atropine	$\beta$ -Estradiol	Niacinamide	3-acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloral hydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine			

### 【BIBLIOGRAPHY】

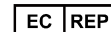
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### Index of Symbols

	Consult instructions for use		Contains sufficient for <n> test		Catalogue number
	In vitro diagnostic medical device		Use-by date		Do not reuse
	Store between 2-30 °C		Batch code		Manufacturer
	Do not use if package is damaged and consult instructions for use		Authorized Representative in EU		



**Hangzhou AllTest Biotech Co.,Ltd.**  
 #550, Yinhai Street  
 Hangzhou Economic & Technological Development Area  
 Hangzhou, 310018 P.R. China  
 Web: www.alltests.com.cn Email: info@alltests.com.cn



MedNet EC-REP GmbH  
 Borkstrasse 10,  
 48163 Muenster,  
 Germany

Number:  
 Revision due