

SCREEN®

Multi-Drug Rapid Test Cassette (Hair)

Package Insert

A rapid test for the qualitative detection of COT/MET/MOP/COC in human hair. 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 hair at the following cut-off concentrations:

Test	Calibrator	Cutoff(ng/mg)
COT	Cotinine	0.2
MET	d-Methamphetamine	0.2
MOP	Morphine	0.2
COC	Cocaine	0.5

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】

Hair detection has unique advantages in the field of drug testing. Hair can provide long-term medication information that is not available in other biological samples such as blood and urine. 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.

Cotinine (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

Morphine (MOP)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, oversensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking.

【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 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 appear in the test region.

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

Catalyst Powder can be stored at 2-30°C for up to 18 months prior to testing. However it is enzyme-based reagent that work 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 Catalyst 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 Cards
- Buffer
- Specimen Collection Tubes with Catalyst Powder
- Materials Required But Not Provided
- Specimen Collection Containers
- Timer
- Scissors

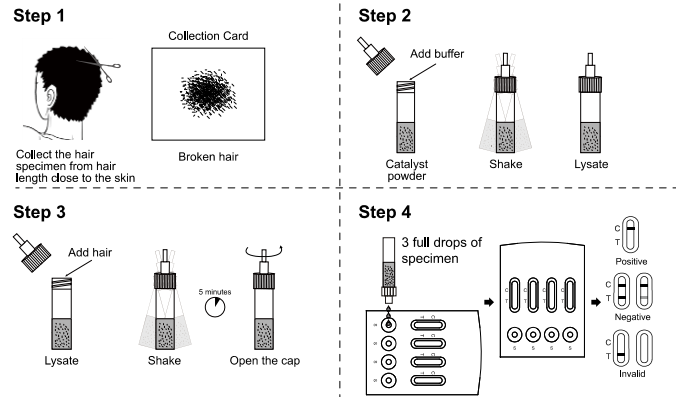
【DIRECTIONS FOR USE】

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

- Collect the hair specimen from **hair length 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 to the Specimen Collection Tube with Catalyst 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 vigorously to mix the specimen and the lysate. Leave the tube alone for 5 minutes
- 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 **3 full drops of specimen (Lysate)** (approx. 120 µL) to 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 a 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 for the target analyte.

*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 region (T). The positive result means that the target analyte concentration in the hair sample is greater than the designated cut-off for the target analyte.

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. 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.

【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 Multi-Drug Rapid Test Cassette (Hair) 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
	Positive	Negative	
Multi-Drug Rapid Test Cassette	Positive	6	90.0%
	Negative	68	91.9%
COT	Positive	27	90.3%
	Negative	3	91.5%
MET	Positive	28	90.9%
	Negative	3	91.7%
MOP	Positive	30	90.9%
	Negative	3	91.7%
COC	Positive	30	90.9%
	Negative	3	92.2%

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 0.2ng/mg		MET 0.2ng/mg		MOP 0.2ng/mg		COC 0.5ng/mg	
	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	25	5	27	3	26	4	26	4
Cut-off	15	15	15	15	15	15	15	15
+25% Cut-off	4	26	3	27	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30
+300% Cut-off	0	30	0	30	0	30	0	30

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)
COT			
(-)-Cotinine	0.2	(-)-Nicotine	5
MET			
p-Hydroxymethamphetamine	5	(±)-3,4-Methylenedioxy-methamphetamine	2.5
D-Methamphetamine	0.2	L-Methamphetamine	10
MOP			
6-Monoacethylmorphine	0.2	Morphine	0.2
COC			
Cocaine			0.5

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:

COT	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
0.1	10	10	0	10	0	10	0
0.15	10	8	2	8	2	9	1
0.25	10	2	8	3	7	1	9
0.3	10	0	10	0	10	0	10

MET	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
0.1	10	10	0	10	0	10	0
0.15	10	8	2	8	2	9	1
0.25	10	2	8	3	7	1	9
0.3	10	0	10	0	10	0	10

0	10	10	0	10	0	10	0
0.1	10	10	0	10	0	10	0
0.15	10	8	2	8	2	9	1
0.25	10	1	9	2	8	2	8
0.3	10	0	10	0	10	0	10

MOP

MOP	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
0.1	10	10	0	10	0	10	0
0.15	10	8	2	8	2	9	1
0.25	10	1	9	2	8	1	9
0.3	10	0	10	0	10	0	10

COC

COC	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
0.25	10	10	0	10	0	10	0
0.375	10	8	2	8	2	9	1
0.625	10	1	9	2	8	1	9
0.75	10	0	10	0	10	0	10

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 Cotinine, Methamphetamine, Morphine, Cocaine. 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	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Isoxsuprine	Sulfamethazine
l-Ascorbic acid	Digoxin	d,l-Propranolol	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone
Atropine	β-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】

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
2. Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
3. Ambre J. *J. Anal. Toxicol.* 1985; 9:241.
4. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
5. Robert DeCresce. *Drug Testing in the workplace*, 1989 page 114.
6. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216
7. C. Tsai, S.C. et.al., *J. Anal. Toxicol.* 1998; 22 (6): 474
8. Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 6th Ed. Biomedical Publ., Foster City, CA 2002.

