

STAT
HAIR TEST™

Multi-Drug Hair Test

Catalog No.: See Box label

For forensic use only.**INTENDED USE**

STATHAIR TEST™ Multi-Drug Hair Test offers qualitative detection of the following drugs of abuse and their principal metabolites in human hair at specified cut-off levels: Amphetamine (AMP), Barbitol (BAR), Cocaine (COC), Methamphetamine (MET/mAMP), Opiate (OPI), Oxycodone (OXY), Phencyclidine (PCP).

Drug (Identifier)	Calibrator	Cut-off level
Amphetamine (AMP)	D-Amphetamine	500 pg/mg
Barbitol (BAR)	Secobarbital	200 pg/mg
Cocaine (COC)	Benzoylcegonine	500 pg/mg
Methamphetamine (MET/mAMP)	D-Methamphetamine	200 pg/mg
Opiate (OPI)	Morphine	200 pg/mg
Oxycodone (OXY)	Oxycodone	200 pg/mg
Phencyclidine (PCP)	Phencyclidine	300 pg/mg

STATHAIR TEST™ Multi-Drug Hair Test is intended to detect for evidence of drug consumption.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS OR LC-MS is the recommended confirmatory method.

PRINCIPLE

This test employs competitive immunochromatography method to detect the presence of Amphetamine (AMP), Barbitol (BAR), Cocaine (COC), Methamphetamine (MET/mAMP), Opiate (OPI), Oxycodone (OXY), Phencyclidine (PCP) in human hair specimens. After the hair specimen is collected from the donor, it is placed in the hair processing tube containing dissolving solution and grinding beads. The hair process tube is then put into the hair processor, enhancing the exposure of analytes. After centrifuge, the specimen is transferred to the test cube. Where the analyte will react with the reagents contained in the test strips.

During testing, the hair specimen mixes with the drug-specific monoclonal antibody conjugate, and flows across the membrane. When sample drug levels are zero or below the target cutoff, drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region. This produces a colored band in the Test Region that, regardless of its intensity, indicates a negative result.

When drug concentration in the sample are at or above the target cutoff, the drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region. This prevents the development of a colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region if the test has been performed properly.

PRECAUTIONS

- The test kit is for external use only. Do not swallow.
- Discard after use. The test kit cannot be used more than once.
- Do not use the test kit beyond expiration date.
- Do not use the test kit if the pouch is punctured or not well sealed.
- Discard all the components as medical waste after testing.
- Do not overload the hair processing tube, recommend adding 30 mg±5 mg of hair specimen and no more than 50 mg.
- Use appropriate precautions in the collection, handling, storage and disposal of donor's sample and kit contents. Use of powderless gloves, protective eyewear and

- laboratory coat is recommended when handling the specimens.
- Wash hands thoroughly afterwards.

MATERIAL**Materials Provided**

- 25 Hair test cubes, each in one pouch with two desiccants. The desiccants are for storage purposes only and are not used in the test procedure.
- 25 Hair processing tubes (1.5mL/tube), each tube contains:
 - Grinding bead
 - Hair dissolving solution containing 0.05% sodium azide.
- 1 Package Insert

Material Required but Not Provided

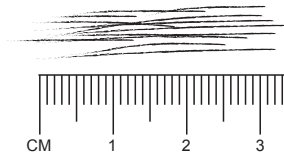
- Timer or clock
- Hair collection kit: Scissors and tweezers hair clips, alcohol wipe,
- Electronic balance (precision 0.001g or lower)
- Hair processor
- Gloves, laboratory coat and protective eyewear.

STORAGE AND STABILITY

- Store at 4°C-30°C (39°F-86°F) in the sealed pouch up to the expiration date. See expiry date on the pouch.
- Keep away from direct sunlight, moisture and heat.
- Use the hair test cube within 1 hour after opening the foil pouch.
- DO NOT FREEZE

SPECIMEN COLLECTION

For hair specimen collection, clip the hair specimen 3 cm from the scalp, the quantity should be 30 mg±5 mg, make sure the scissors and tweezers are clean. The following is the example of 30 mg hair specimen.



30 mg hair schematic diagram

- At room temperature, the specimens should be tested immediately after collection.
- Processed hair specimen solution can be valid for 5 days at 4°C-30°C (39°F-86°F). Shake well the processed hair specimen before test.
- DO NOT contaminate the hair specimen.

Notes about collection:

- If necessary, obtain additional specimens of hair from other regions of the head.
- With shaved/short hair, locate longest hair possible and make multiple cuts from different locations to produce sufficient amount of hair needed.

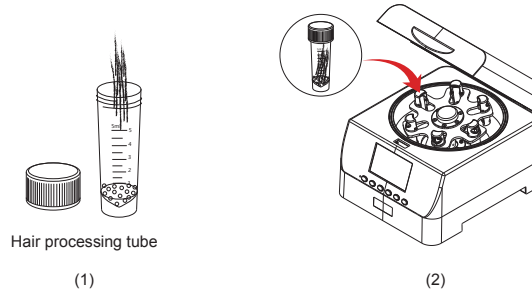
For detailed hair collection instructions, please refer to the collection user manual that provided by manufacturer or distributor.

TEST PROCEDURE

Please read the instructions carefully before testing. Test should be performed at room temperature 18°C-30°C (65°F-86°F).

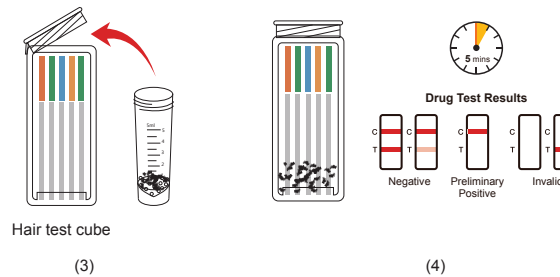
- Remove the hair test cube from the foil pouch by tearing at the notch. Take out the hair processing tube from the kit. Lay the test cube on the table, and mark it.
- Put the hair specimen into a hair processing tube, tightly screw the cap onto the tube. (Figure (1)).
- Put the processing tube into the hair processor (Figure (2)); set the parameters (refer to the user manual of hair processor).

- Start the machine for processing. Take out the processing tube and pour all the contents into the testing cube (Figure (3)).
- Read results at 5 minutes. Do not read after 10 minutes. (Figure (4))



(1)

(2)



Hair test cube

(3)

(4)

INTERPRETATION OF RESULTS**Negative (-)**

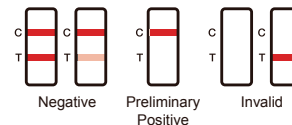
A colored band is visible in each Control Region (C) and the appropriate Test Region (T).

Preliminary Positive (+)

A colored band is visible in each Control Region (C). No colored band appears in the appropriate Test Region (T).

Invalid

If a colored band is not visible in each of the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.



Negative

Preliminary Positive

Invalid

Note: There is no meaning attributed to line color intensity or width.

TEST LIMITATIONS

- Proper specimen collection, storage and processing are critical to the performance of the test. Carefully read the instruction of use prior to testing.
- The assay provides a qualitative, preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary results are positive.

- This test is used to detect the certain drugs or metabolites in hair. Hair growing speed and drug abuse frequency and amount may affect the testing results. For example, if the result is negative, it doesn't absolutely mean that the drugs were not taken. It may be that small amount of drug was taken, which produces lower concentration than the cutoff level, or may be that the drugs were taken a very short period ago. If the drug abuse is still suspended, other testing methods should be considered.
- Clinical consideration and professional judgment should be applied to any drug of abuse test result.
- Passive exposure to drugs can possibly cause positive result.

PRODUCT PERFORMANCE**1. ACCURACY**

A side-by-side comparison was conducted using the STATHAIR TEST™ Hair Test and LC-MS. A total of 921 hair specimens were analyzed. Results were as followed:

AMP

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	20	5	25
Negative	0	134	134
Total	20	139	159

Positive agreement rate: 100.00% (95% CI:83.16%~100.00%)

Negative agreement rate: 96.40% (95% CI:91.81%~98.82%)

The total agreement rate: 96.86% (95% CI:92.81%~98.97%)

BAR

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	45	2	47
Negative	3	115	118
Total	48	117	165

Positive agreement rate: 93.75% (95% CI:82.80%~98.69%)

Negative agreement rate: 98.29% (95% CI:93.96%~99.79%)

The total agreement rate: 96.97% (95% CI:93.07%~99.01%)

COC

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	50	1	51
Negative	1	50	51
Total	51	51	102

Positive agreement rate: 98.04% (95% CI:89.55%~99.95%)

Negative agreement rate: 95.04% (95% CI:89.52%~98.16%)

The total agreement rate: 95.93% (95% CI:91.79%~98.35%)

MET/mAMP

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	41	0	41
Negative	0	74	74
Total	41	74	115

Positive agreement rate: 100.00% (95% CI:91.40%~100.00%)

Negative agreement rate: 100.00% (95% CI:95.14%~100.00%)

The total agreement rate: 100% (95% CI:96.84%~100.00%)

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	43	2	45
Negative	0	113	113
Total	43	115	158

Positive agreement rate: 100.00% (95% CI:91.78%~100.00%)

Negative agreement rate: 98.26% (95% CI:93.86%~99.79%)

The total agreement rate: 98.73% (95% CI:95.50%~99.85%)

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	20	2	22
Negative	1	50	51
Total	21	52	73

Positive agreement rate: 95.24% (95% CI:76.18%~99.88%)

Negative agreement rate: 96.15% (95% CI:86.79%~99.53%)

The total agreement rate: 95.89% (95% CI:88.46%~99.14%)

STATHAIR TEST™ Hair Test	LC-MS		
	Positive	Negative	Total
Positive	25	2	27
Negative	2	120	122
Total	27	122	149

Positive agreement rate: 92.59% (95% CI:75.71%~99.09%)

Negative agreement rate: 98.36% (95% CI:94.20%~99.80%)

The total agreement rate: 97.32% (95% CI:93.27%~99.26%)

2. Analytical Sensitivity

In order to test the precision of this product, the standard control confirmed by LC-MS/MS are formulated into different concentrations, which are treated according to hair specimen pre-processing procedure. After that, the final liquid is tested by the hair test cup. Each concentration specimen is tested repeatedly for 20 times to obtain the following results:

Concentration	AMP		BAR		COC		MET/mAMP	
	Negative	Positive	Negative	Positive	Negative	Positive	Negative	Positive
100% cutoff	20	0	20	0	20	0	20	0
-75% cutoff	20	0	20	0	20	0	20	0
-50% cutoff	20	0	20	0	20	0	20	0
-25% cutoff	12	8	15	5	5	15	12	8
cutoff	10	10	12	8	8	12	11	9
+25% cutoff	0	20	0	20	0	20	0	20
+50% cutoff	0	20	0	20	0	20	0	20
+75% cutoff	0	20	0	20	0	20	0	20

Concentration	OPI		OXY		PCP	
	Negative	Positive	Negative	Positive	Negative	Positive
100% cutoff	20	0	20	0	20	0
-75% cutoff	20	0	20	0	20	0
-50% cutoff	20	0	20	0	20	0

-25% cutoff	13	7	10	10	10	10
cutoff	10	10	9	11	8	12
+25% cutoff	0	20	0	20	0	20
+50% cutoff	0	20	0	20	0	20
+75% cutoff	0	20	0	20	0	20

3. Cross-Reactivity

The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

AMP	Concentration
D-Amphetamine	500 pg/mg
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	1300 pg/mg
3,4-Methylenedioxymethamphetamine (MDMA)	160000 pg/mg

BAR	Concentration
Secobarbital	200 pg/mg
Amobarbital	1000 pg/mg
Aprobarbital	5000 pg/mg
Sec-butylbarbital	2500 pg/mg

COC	Concentration
Cocaine	200 pg/mg
Benzoyllecgonine	500 pg/mg
Ecgonine methyl ester	26000 pg/mg
Ecgonine	33000 pg/mg

MET/mAMP	Concentration
D-Methamphetamine	200 pg/mg
Amphetamine	3000 pg/mg
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	1600 pg/mg
(+/-) 3,4-Methylenedioxyethylamphetamine (MDEA)	1600 pg/mg
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2600 pg/mg

OPI	Concentration
Morphine	200 pg/mg
6- acetyl morphine	300 pg/mg
Codeine	160 pg/mg
Dihydromorphinone	3000 pg/mg
Ethyl morphine	160 pg/mg
Oxycodone	3000 pg/mg
Thebaine	3000 pg/mg

OXY	Concentration
Oxycodone	200 pg/mg
6-acetyl morphine	>3000 pg/mg
Buprenorphine	>3000 pg/mg
Dihydrocodeine chloride	6000 pg/mg

Morphine	>3000 pg/mg
Hydromorphone	3000 pg/mg

PCP	Concentration
Phencyclidine	300 pg/mg
Tetrahydrozoline	4000 pg/mg

4. Interference

(1) Hair color doesn't affect the results.

(2) Exogenous substances: Normal hair treatment will not affect the results, such as shampoo, conditioner, gels, spays, etc.

(3) The interfering substance was diluted with processed hair specimen solution to 1500 ng/mg (The substances content per milligram of hair specimen is 1500ng), and then tested with a hair detection cup. This test is not affected by the following substances at the concentration of 1500 ng/mg:

Acyclovir	Enalapril	Paliperidone
Alipirazole	Epinephrine	Papaverine
Amiodarone	Esomeprazole Magnesium	Penfluridol
Amlodipine	Gabapentin	Penicillin V
Amoxicillin	Glibenclamide	Perphenazine
Ampicillin	Gliclazide	Pioglitazone
Aspirin	Glipizide	Piracetam
Atorvastatin	Glucose	Pravastatin
Buspirone	Hydrochlorothiazide	Prednisone
Captopril	Isosorbide Dinitrate	Promethazine
Carbamazepine	Lamotrigine	Propranolol (Except PCP)
Cefaclor	Lansoprazole	Propylthiouracil Tablet
Cefalexin	Levonorgestrel	Quetiapine
Cefradine	Levothyroxine	Rifampicin
Chondroitin	Lidocaine	Sildenafil
Ciprofloxacin	Lisinopril	Simvastatin
Clarithromycin	Lithium Carbonate	Sodium Valproate
Clopidogrel	Loperamide	Spirolactone
Cortisone	Loratadine	Spirolactone
Cyclobenzaprine	Metoprolol	Tetracycline Tablet
Dextromethorphan	Mirtazapine	Tizanidine
Diclofenac	Montelukast	Trazodone
Dicyclomine	Mosapride	Triamterene
Digoxin	Nifedipine	Ursodeoxycholic Acid
Diphenhydramine(Except COC)	Nimodipine	Vitamin B1
Diphenoxylate Hydrochloride	Nitroglycerin	Vitamin B2
Domperidone	Oxymetazoline	Vitamin C(Ascorbic Acid),

BIBLIOGRAPHY

- https://www.samhsa.gov/sites/default/files/meeting/documents/july_2013_moore.pdf
- Logan B K. Review of: Handbook of Workplace Drug Testing, 2nd Edition [J]. Journal of Forensic Sciences, 2009, 54(5).
- Dring L G, Smith R L, Williams R T. The metabolic fate of amphetamine in man and other species. [J]. The Biochemical journal, 1970, 116:425-435.
- Cone E J. Mechanisms of drug incorporation into hair.[J]. Therapeutic Drug Monitoring, 1996, 18(4):438-43.
- Society H T. Recommendations for hair testing in forensic cases [J]. Forensic Science

International, 2004, 145(2-3):83-84.

- Employer Drug Testing Hair Test FAQs---Omega laboratories. <https://www.omegalabs.net/hair/hair-testing-faqs/other-services.cmsx>
- Suárez-García A, Álvarez-Freire I, Bermejo-Barrera A M, et al. Duration of detection of cocaine and metabolites in hair after discontinuation of abuse[J]. Microchemical Journal, 2020, 153: 104335.
- Detection of Basic Drugs (methamphetamine, antidepressants and nicotine) from Human Hair[J]. Forensic Sci., 1993: 63, 85

INDEX OF SYMBOLS



Keep away from sunlight



Store between 4°C - 30°C (39°F - 86°F)



Keep dry



Do not re-use

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