MCAT Rapid Test Dipstick (Urine)
Package Insert

REF DMCA-101	English

A rapid test for the qualitative detection of Methcathinone *in human urine*
For medical and other professional in vitro diagnostic use only.

【INTENDED USE】
The MCAT Rapid Test Dipstick (Urine) is a rapid chromatographic immunoassay for the detection of methcathinone in urine at a cut-off concentration of 500ng/ml. This test will detect other related compounds, please refer to the 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】
Methcathinone，is a monoamine alkaloid and psychoactive stimulant, a substituted cathinone. Methcathinone is a highly addictive drug, primarily psychologically addicting and most of the signs of addiction to the drug are emotional or psychological. It has been popularized and continues to be sold under misleading names such as "bath salts", "plant fertilizers" or "research chemicals", but it is actually a powerful psycho-stimulant used as a recreational drug. Effects of this drug typically last from 4 to 6 hours. It is used as a recreational drug due to its potent stimulant and euphoric effects and is considered to be addictive, with both physical and psychological withdrawal occurring if its use is discontinued after prolonged or high-dosage administration [1]. It is usually snorted, but can be smoked, injected, or taken orally. Methcathinone is listed as a Schedule I controlled substance by the Convention on Psychotropic Substances and the United States' Controlled Substances Act, and as such it is not considered to be safe or effective in the treatment, diagnosis, prevention, or cure of any disease, and has no approved medical use. Methcathinone has very strong affinities for the dopamine transporter and the norepinephrine (noradrenaline) transporter. Its affinity for the serotonin transporter is less than that of methamphetamine. [2]
Effects of short term intoxication are similar to those produced by crack cocaine or methamphetamine: stimulation of heart rate and respiration; feeling of euphoria; loss of appetite; increased alertness; pupils may be dilated; body temperature may be slightly elevated. Acute intoxication at higher doses may also result in: insomnia, tremors and muscle twitching, fever, headaches, convulsions, irregular heart rate and respirations, anxiety, restlessness, paranoia, hallucinations and delusions.

【PRINCIPLE】
The MCAT Rapid Test Dipstick (Urine) 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. Methcathinone, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized methcathinone-protein 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 methcathinone level exceeds the cut-off level, because it will saturate all the binding sites of anti-methcathinone antibody.
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-methcathinone antibody coupled particles and methcathinone-protein conjugate. A goat 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 or label of the closed canister. The test must remain in the sealed pouch or closed canister 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 a clear specimen for testing.

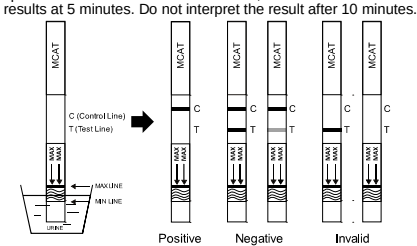
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided
- Test Dipsticks
- Package insert

Materials Required But Not Provided
- Specimen collection container
- Timer

【DIRECTIONS FOR USE】
Allow the test, urine specimen, and/or controls to reach room temperature (15-30ºC) prior to testing.
1.Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and use it within one hour.
2.With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.
3.Place the Test Dipstick on a non-absorbent flat surface, start the timer and 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:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the methcathinone concentration is below the detectable cut-off level.
***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.
POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the methcathinone concentration exceeds the detectable cut-off 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 kit immediately and contact your local distributor.

【QUALITY CONTROL】
A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】
1. The MCAT Rapid Test Dipstick (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (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 methcathinone concentration is below the detectable level of 500ng/ml. Positive result means the concentration of methcathinone is above the level of 500ng/ml. The MCAT Rapid Test Dipstick has a sensitivity of 500ng/ml

【PERFORMANCE CHARACTERISTICS】
A side-by-side comparison was conducted using The MCAT Rapid Test Dipstick and GC/MS at the cut-off of 500ng/ml. Testing was performed on 102 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
MCAT Rapid Test Dipstick	Results	Positive	Negative	
	Positive	20	4	24
	Negative	2	76	78
Total Results		22	80	102
% Agreement		90.9%	95.0%	94.1%

Analytical Sensitivity
A drug-free urine pool was spiked with methcathinone at the following concentrations: 0ng/ml, 250ng/ml, 375ng/ml, 500ng/ml, 625ng/ml, 750ng/ml and 1500ng/ml. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Methcathinone Concentration (ng/ml)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
250	-50%	30	30	0
375	-25%	30	28	2
500	Cut-off	30	17	13
625	+25%	30	3	27
750	+50%	30	0	30
1500	3X	30	0	30

Analytical Specificity
The following table lists compounds that are positively detected in urine by the MCAT Rapid Test Dipstick (Urine) at 5 minutes.

Compound	Concentration (ng/ml)	Compound	Concentration (ng/ml)
S(-)-Methcathinone HCl	500	R(+)-Methcathinone HCl	1500
Methoxyphenamine	100000	3-Fluoromethcathinone HCl	1500

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 Dipstick of coded specimens containing, according to GC/MS, no methcathinone, 25% above and below the cut-off and 50% above and below the cut-off of methcathinone was provided to each site. The following results were tabulated:

Methcathinone Concentration (ng/ml)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
250	10	10	0	10	0	10	0
375	10	9	1	8	2	9	1
625	10	2	8	2	8	2	8
750	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity
Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 250ng/ml and 750ng/ml of methcathinone. The MCAT Rapid Test Dipstick (Urine) 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 methcathinone to 250ng/ml and 750ng/ml. The spiked, pH-adjusted urine was tested with The MCAT Rapid Test Dipstick (Urine) 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 methcathinone positive urine. The following compounds show no cross-reactivity when tested with The MCAT Rapid Test Dipstick (Urine) at a concentration of 100 μg/ml.

Non Cross-Reacting Compounds

Acetophenetidin（phenacetin）	Promethazine	Fluoxetine
N-Acetylprocainamide（acecainide）	Papaverine	Metoprolol
Acetylsalicylic acid（aspirin）	Penicillin	Amantadine
AminopyrineAminophenazone	Perphenazine	Chlorpropamide
Amitriptyline	Phenelzine	Clozapine
Amobarbital	Phenobarbital	Baclofen
Amoxcillin	l-Phenylephrine (R)-(-)-Phenylephrine	Amikacin
Aspartame Asp-Phemethylester	β-Phenylethylamine	Droperidol
Atropine	Prednisolone	Gentamicin
Benzilic acid	Prednisone	Indomethacin
Benzoic acid	Procaine	Sulfamethoxazole
Bilirubin	Quinidine	Sulfisoxazole
Chloramphenicol	Quinine	Salbutamol
Chlorothiazide	Serotonin (5-Hydroxytryptamine)	Tobramycin
Chlorpromazine	Sulfamethazine	Zopiclone
Chloroquine	Temazepam（	Cephalexin
Cholesterol	Tetracycline	Clindamycin
Clomipramine	Tetrahydrozoline	Dexamethasone
Clonidine	Thiamine（vitamine B1）	Dicumarol
Cocaine	Thioridazine	Carisoprodol
Cortisone	d,l-Tyrosine L-Tyrosine	Metoclopramide
(-)Cotinine	Tolbutamide	(+)-cis-Diltiazem
Creatinine	Triamterene	Protriptyline
Dextromethorphan	Trimethoprim	Haloperidol
Diazepam	Tryptamine	Procyclidine
Diclofenac	d,l-Tryptophan	Metronidazole
Diflunisal	Uric acid	Vancomycin
Digoxin	Verapamil	Spironolactone
Diphenhydramine	Zomepirac	Emetine
Doxylamine	Ampicillin	Sertraline
Erythromycin	Caffeine	Heroin (diacetylmorphine)
β-Estradiol Estradiol	(+/-)-Chlorpheniramine	R(+)-Cathinone
Estrone-3- Sulfate	Ranitidine	S(-)-Cathinone
Ethyl-p-aminobenzoate (Benzocaine)	Quinacrine	Barbital
Fenoprofen	Trans-2-Phenylcyclopropylamine (1R, 2S) - (-)-Ephedrine=184 l-Ephedrine	Lansoprazole
Furosemide	Dicyclomine	Aprobabital
Gentisic acid	Trazodone	Butalbital（Tetrallobarbital）
Hydralazine	Nimesulide	Butethal
Hydrochlorothiazide	Buspirone	Cyclopentobarbital
Hydrocodone	l-Thyroxine	Estazolam
O-Hydroxyhippuric acid	（2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine）	Lorazepam
p-Hydroxymethamphetamine	Oxymorphone	Lorazepam glucuronide
3-Hydroxytyramine (Dopamine)	Cyclobenzaprine	Midazolam
Ibuprofen	Lidocaine	Nitrazepam
Imipramine	Guaiacol Glyceryl Ether carbamate	Triazolam
(-) Isoproterenol [(-)isoprenaline]	Guaiacol Glyceryl Ether	Alprazolam
Isoxsuprine	Amoxapine	Clobazam
Ketoprofen	(+)- Chlorpheniramine	3,4-Methylenedioxyethylamphetamine（3,4-MDE）
Labetalol	Chlorprothixene（meprobamate）	Nortriptyline
Maprotiline	R (-)Deprenyl （selegiline）	Doxepin
Methadone	Pheniramine	Desipramine
Meperidine（Pethidine）	4-Dimethylaminoantipyrine	Nordoxepin
Methoxyphenamine	Riboflavin（vitamine B2）	p-Acetamidophenyl-β-D-glucuronide
Methylphenidate（ritalin）	α -Naphthaleneacetic Acid	(s)-(+)-mathoxy-α-mathel-2-naphaleneacetic acid
Nalidixic acid	(+/-) Epinephrine	JWH-0185-pentanoic acid metabolite
Naloxone	Ephedrine	Tramadol Hydrochloride
Naltrexone	Phenothiazine	Venlafaxine Hydrochloride
Niacinamide（nicotinamide）	Albumin	Quetiapine Fumarate
Nifedipine	d (+) Glucose	Trocamide
Norethindrone Norethisterone	Sodium chloride	Pregabalin
d-Norpropoxyphene	Pemoline	Oxymetazoline
Noscapine	Disopyramide	Etodolac
d,l- Octopamine	Lindane (Hexachlorocyclohexane)	
Oxazepam		

【BIBLIOGRAPHY】
1. Calkins RF, Aktan GB, Hussain KL (1995). "Methcathinone: the next illicit stimulant epidemic?" Journal of Psychoactive Drugs 27 (3): 277–85. doi:10.1080/02791072.1995.10472472. PMID 8594170
2. Rothman, B. R.; et al. (June 2003). "In Vitro Characterization of Ephedrine-Related Stereoisomers at Biogenic Amine Transporters and the Receptorome Reveals Selective Actions as Norepinephrine Transporter Substrates". The Journal of Pharmacology and Experimental Therapeutics. 307 (1): 138–45.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit
IVD	For in vitro diagnostic use only		Use by
2°C 30°C	Store between 2-30°C	LOT	Lot Number
	Do not use if package is damaged		

EC REP	Authorized Representative
	Do not reuse
REF	Catalog #

Hangzhou AllTest Biotech Co., Ltd.
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