MDMA Surface Test Panel
Package Insert

REF DMD-X14	English

【INTENDED USE】

The MDMA Surface Test Panel is a rapid immunochromatographic assay for the qualitative detection of Methylenedioxymethamphetamine at the cut-off of 500 ng/mL.

With this surface test, you can test:

1. Minimal traces of drugs adhering to surfaces such as furniture, utilitarian objects etc. as residues.
2. Solid substances such as tablets and powder.
3. Urine samples, which can be used to detect drug use.
4. Liquids from ampoules or other containers that may contain suspicious substances.

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. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

【SUMMARY】

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The Methylenedioxymethamphetamine assay contained within the MDMA Surface Test Panel yields a positive result when the MDMA concentration exceeds 500 ng/mL.

【PRINCIPLE】

During testing, the specimen migrates upward by capillary action. A drug, if present in the specimen 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 form in the test region.

A drug-positive specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative 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 at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

The test contains membrane strip coated with methylenedioxymethamphetamine-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to methylenedioxymethamphetamine.

【PRECAUTIONS】

- Use only once.
- Do not touch the free endings of the strip to avoid contamination.
- Do not dip the panel above the maximum deepness level mark.
- Do not spill the samples into the reaction zone.
- Specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Do not use the test after expiration date.
- Do not use the test after damage of the packaging foil.
- Use test right after unwrapping.
- Please take the specificity and the cross reactivity into account for evaluation.
- **Strong acid, alkali, oxidation and corrosion liquid is not suitable for this test, thick, oily liquid is not suitable for this test.**

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test panel must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

【MATERIALS】

Materials Provided

- Test panels
- Package insert

Materials Required but Not Provided

- Specimen collection containers
- Timer

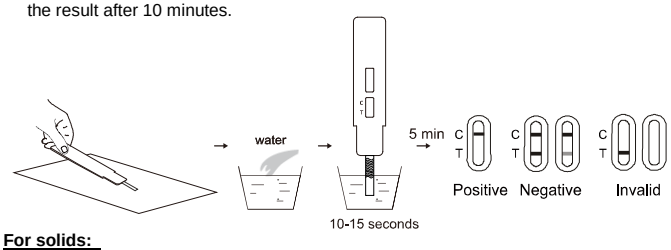
【DIRECTIONS FOR USE】

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

Remove the test panel from the sealed pouch and use it as soon as possible.

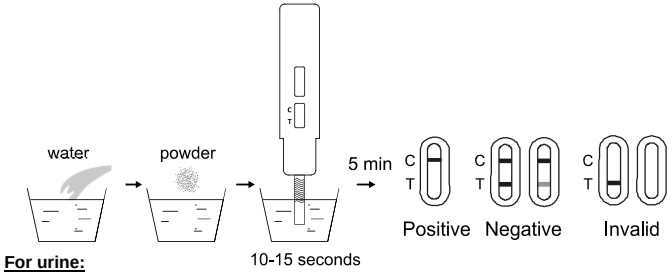
For surfaces:

1. Remove the panel cap and wipe with the panel over the surface in which the drugs are suspected.
2. With the arrow pointing toward the water, **immerse the test panel vertically in the water for at least 10 to 15 seconds**. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored lines to appear, **read the results at 5 minutes**. Do not interpret the result after 10 minutes.



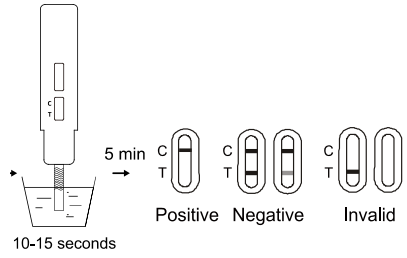
For solids:

1. Prepare specimen collection containers and solid sample.
2. Pour solid sample into the specimen collection containers.
3. At least **1mg solid diluted with 5mL water** (1 mineral water bottle cap≈5mL). Shake to mix well.
4. Remove the panel cap, with the arrow pointing toward the water **immerse the test panel vertically in the diluted specimen for at least 10 to 15 seconds.** Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
5. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



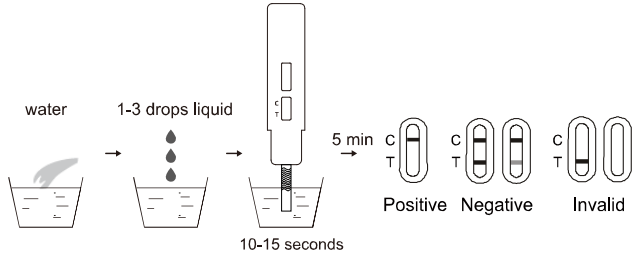
For urine:

1. Collect urine in a clean and dry container.
2. Remove the panel cap, with the arrow pointing toward the specimen, **immerse the test panel vertically in the specimen for at least 10 to 15 seconds.** Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



For liquids:

1. Prepare specimen collection containers and liquid sample.
2. Pour **one to three drops of suspicious liquid into 5mL water** (1 mineral water bottle cap≈5mL). Shake to mix well.
3. Remove the panel cap, with the arrow pointing toward the specimen, i**mmerse the test panel vertically in the specimen for at least 10 to 15 seconds**. Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Wait for the colored lines to appear, **read the results at 5 minutes** and 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 region (T). This negative result means that the concentrations in the sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored lines(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 drug concentration in the sample is greater than the designated cut-off for a specific drug.

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 local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A line appearing in the control 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 practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The MDMA Surface Test Panel provides only a qualitative, preliminary 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. A negative result may not necessarily indicate drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.
3. This test does not distinguish between drugs of abuse and certain medications.[1,2]

【PERFORMANCE CHARACTERISTICS】

Accuracy

A comparison was conducted using the MDMA Surface Test Panel and GC/MS. The following results were tabulated:

Method		GC/MS		Total Results
MDMA Surface Test Panel	Results	Positive	Negative	
	Positive	102	1	103
	Negative	2	145	147
Total Results		104	146	250
% Agreement		98.1%	99.3%	98.8%

Analytical Sensitivity

The following table lists different concentration drugs that are detected by the MDMA Surface Test Panel at 5 minutes.

MDMA 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	25	5
500	Cut-off	30	15	15
625	+25%	30	3	27
750	+50%	30	0	30
1,500	300%	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected by the MDMA Surface Test Panel at 5 minutes.

Compound	Concentration (ng/mL)
(±) 3,4-Methylenedioxy methamphetamine HCl	500
(±) 3,4-Methylenedioxyamphetamine HCl	3,000
3,4-Methylenedioxyethyl-amphetamine	300

Precision

A study was conducted at three sites 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:

MDMA 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	8	2	9	1	9	1
625	10	1	9	1	9	1	9
750	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 or Methylenedioxymethamphetamine positive specimen. The following compounds show no cross-reactivity when tested with the MDMA Surface Test Panel at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Dextromethorphan	Meprobamate	Procaine
Acetophenetidin	Diclofenac	Methamphetamine	Promazine
N-Acetylprocainamide	Diazepam	Methadone	Promethazine
Acetylsalicylic acid	Diflunisal	Methoxyphenamine	D,L-Propranolol
Aminopyrine	Digoxin	Methylphenidate	D-Propoxyphene
Amitryptyline	Dicylomine	Verapamil	D-Pseudoephedrine
Amobarbital	Diphenhydramine	Zomepirac	Quinacrine
Amoxicillin	5,5 - Diphenylhydantoin	Morphine sulfate	Quinidine
Ampicillin	Doxylamine	Nalidixic acid	Quinine
L-Ascorbic acid	Ecgonine hydrochloride	Naloxone	Ranitidine
D-Amphetamine	Ecgonine methylester	Naltrexone	Salicylic acid
Uric acid	(-) -ψ-Ephedrine	Naproxen	Secobarbital
L-Amphetamine	[1R,2S](-) Ephedrine	Niacinamide	Serotonin
Apomorphine	L – Epinephrine	Nifedipine	(5-Hydroxytyramine)
Aspartame	Erythromycin	Nimesulidate	Sulfamethazine
Atropine	β-Estradiol	Norcodein	Sulindac
Benzilic acid	Estrone-3-sulfate	Norethindrone	Sustiva
Benzoic acid	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Temazepam
Benzoylecgonine	Fenoprofen	Noscapine	Tetracycline
Benzphetamine	Furosemide	D,L-Octopamine	Prednisolone
Bilirubin	Gentisic acid	Oxalic acid	Prednisone
(±) - Brompheniramine	Hemoglobin	Oxazepam	Tetrahydrocortisone
Buspiron	Hydralazine	Oxolinic acid	3-(β-D glucuronide)
Caffeine	Hydrochlorothiazide	Oxycodone	Tetrahydrozoline
Cannabidiol	Hydrocodone	Oxymetazoline	Thebaine
Cannabinol	Hydrocortisone	Papaverine	Theophynine
Chloralhydrate	O-Hydroxyhippuric acid	Penicillin-G	Thiamine
Chloramphenicol	p-Hydroxyamphetamine	Pentazocine	Meperidine
Chlordiazepoxide	Creatinine	hydrochloride	Mephentermine
Chlorothiazide	Deoxycorticosterone	Pentobarbital	Thioridazine
(±) - Chlorpheniramine	3-Hydroxytyramine	Perphenazine	Tolbutamide
Chlorpromazine	Imipramine	Phencyclidine	Trazodone
Chlorquine	Iproniazid	Phenelzine	D,L-Tyrosine
Cholesterol	(±) - Isoproterenol	Phenobarbital	Triamterene
Clomipramine	Isoxsuprine	Phentermine	Trifluoperazine
Clonidine	Ketamine	Trans-2-phenyl	Trimethoprim
Cocaethylene	Ketoprofen	cyclopropylamine	Trimipramine
Cocaine hydrochloride	Labetalol	hydrochloride	Tryptamine
Codeine	Levorphanol	L-Phenylephrine	D,L-Tryptophan
Cortisone	Loperamide	β-Phenylethylamine	Tyramine
(-) Cotinine	Maprotiline	Phenylpropanolamine	
D,L-Amphetamine sulfate	p-Hydroxy-methamphetamine	Tetrahydrocortisone, 3- Acetate	Trans-2-phenylcyclopropylamine
Morphine-3-β-D-glucuronide			

【BIBLIOGRAPHY】

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Edition. Biomedical Publications, Foster City, CA. 2002; 744-747.
2. Hardman JG, Limbird LE. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Caution		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use
	Manufacturer				

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

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