

Methamphetamine Card Test

INTENDED USE

The OneStep Methamphetamine Card Test is a rapid qualitative, competitive binding immunoassay for the determination of methamphetamine in human urine.

Always justify preliminary positive and negative results with compelling clinical evidence and professional judgment. The test provides only preliminary data that should be confirmed by other methods such as GC/MS.¹⁻³

INTRODUCTION

The OneStep Methamphetamine Card Test is an easy, fast, and visually read screening method without the need for instrumentation. The test system employs unique polyclonal antibodies to selectively identify methamphetamine in urine samples with a high degree of sensitivity. Methamphetamine and its metabolites are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well-being.⁴ Large doses and extended usage can result in higher tolerance levels and physiological dependency and may lead to substance abuse. D-methamphetamine is a controlled substance. The legally allowable level for methamphetamine is set at 500 ng/ml in urine using the GC/MS detection method by the U.S. National Institute on Drug Abuse.⁵

PRINCIPLE OF THE TEST

The OneStep Methamphetamine Card Test is a chromatographic absorbent device in which drug or drug metabolites in a sample compete with drug conjugate immobilized on a porous membrane support for limited antibody sites. Labeled antibody-dye conjugate mixes with sample specimen and binds to the free drug present forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the test zone preventing the formation of a pink-rose color band when the drug is above the detection level of 500 ng/ml. Unbound dye conjugate binds to the reagent in the control zone and produces a pink-rose color band, demonstrating that the reagents and device are functioning correctly. A negative specimen produces two distinct color bands, one in the test zone and one in the control zone. A positive specimen produces only one color band in the control zone.

REAGENTS AND MATERIALS SUPPLIED

1. Test Device
2. Dropper.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use kit beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.

STORAGE

Store the test kit at room temperature (15-28°C). Refer to the expiration date for stability.

SAMPLE COLLECTION AND PREPARATION

Collect a urine sample in clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze samples (-20°C or below). Bring frozen or refrigerated samples to room temperature before testing. Urine samples exhibiting visible

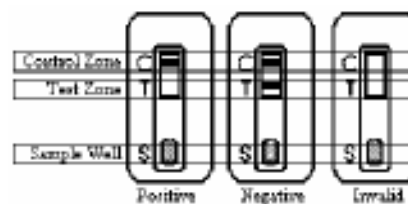
precipitates should be filtered, centrifuged, or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE

1. Bring the test components and urine sample to room temperature (15-28°C) before testing.
2. Do not break the seal on the foil pouch until ready to perform the test.
3. Open the foil pouch at the notch and remove the test device and dropper. Place the test device on a clean, level surface.
4. Holding the dropper vertically, dispense two to three (2-3) full drops of urine without air bubbles into the sample well "S" of the test device.
5. Read the test result at five minutes.

IMPORTANT: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



1. **Positive:** A rose-pink color band appears in the control zone "C" but not in the test zone "T". This is a positive result and indicates the methamphetamine level is at or above the detection sensitivity of 500 ng/ml.
2. **Negative:** Two horizontal rose-pink color bands appear, one in the control zone "C" and one in the test zone "T". This is a negative result and indicates the methamphetamine level is below the detection sensitivity of 500 ng/ml.
3. **Invalid:** If no bands appear, or a test band appears without a control band, disregard the results. The presence of a control line is necessary to validate test performance.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. The use of an external control is recommended to verify proper kit performance.

Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS

1. This product is designed for use with human urine only.
2. Although the test is very accurate, there is a possibility false results will occur due to the presence of interfering substances in the urine.

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3. The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.

4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen and retest.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** The OneStep Methamphetamine Card Test detects methamphetamine and the major metabolites of methamphetamine in urine at concentrations equal to or greater than 500 ng/ml, which is much lower than the level normally found in the urine of regular users of methamphetamine.

2. **Specificity:** A study was conducted with the *OneStep* Methamphetamine Card Test to determine the cross-reactivity of non-methamphetamine related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in **Table 1**.

A separate study was conducted to determine the cross-reactivity of methamphetamine-related compounds with the test. Substances listed in **Table 2** produced results approximately equivalent to the cutoff level for methamphetamine.

Table-1: Compounds tested and found not to cross-react with the test.

Compound / Concentration in mg/ml

Acerophenaddin 100	Guatacol Glyceryl
Acetophenendin 100	Ether Carbonate 226
N-Acetylprocainamide 200	Glucuronic acid 200
Acetylsalicylic acid 300	Glutethimide 100
Amitriptyline 100	5-Hydroxytryptamine 100
Amohurhtal 100	Hippuric acid 200
Amoxicillin 130	Hydralazine 100
1-Amphetamine 100	Hydrochlorothiazide 100
Apomorphine 100	Hydrocodone 100
ASP-PHE Methyl Ester 100	Hydrocortisone 130
Aiopine 100	Hydromorphone 100
Bercilic Acid 300	(-)-Hydroxyhippuric acid 140
Benznoic Acid 280	3-Hydroxyryramine 160
Benzoylgonine 100	Ibuprofen 100
Benzphetamine 100	Imipramine 190
Butabarhital Sodium 100	(-) Isoproterenol 120
Cannabidol 100	Isoxsuprine 130
Chloral Hydrate 100	Ketamine 130
Chlorothiazide 320	Ketoprofen 140
Chlorpromazine 100	Labetalol 100
Chloroquine 330	Levorphanol 100
Cholesterol 160	Lidocaine 100
Clomipramine 230	Loperamide 150
Clonidine 100	Mapronline 140
Cocaine 100	Meperidine 100
Codeine 100	Meprohamate 100
Cortisone 120	Methadone 100
(-) Collinine 100	Methaqualone 100
Creatinine 190	(S)-6-methoxy-a-methyl-naphthaleneacetic acid 250
Deoxycorticosterone 1702	Methylphenidate 100
Dextromethorphan 100	Methypyrylon 100
Diazepam 100	Morphine-3- -D- glucuronide 100
Dicloferiac 100	Nalidixic acid 130
Diflunisal 100	Nalorphine 100
Digoxin 150	Naloxone 100
Diphenhydramine 200	Naltrexone 100
4-Dimethylamantipyrene 100	Niacinamide 170
Daxylamine 100	Nifedipine 140
(+) Ephedrine 130	Norcodeine 100
(+) Ephedrine 160	Norethindrone 100
d-y-Ephedrine 290	

Erythromycin 150	d-Norpropoxyphene 100
h-Estradiol 110	Noscapine 100
Estrone-3-sulfate 100	Nylidrin 190
Ethyl-p-aminobenzoate 180	d, 1-Octopamine 190
Furoxemide 150	Oxalic acid 400
Gentisic acid 120	Oxolinic Acid 110
Oxycodone 100	Sulindac 120
Oxymetazoline 100	Temazepam 100
Papaverine 120	Tetracycline 200
Penicillin-G 120	Tetrahydrocortisone 100
Pentazocaine 100	Tetrahydrozoime 100
Perphenazine 140	Thebaine 100
Phendimetrazine 100	Thlamine 120
Phenelzine 350	Thioridazine 110
Phenobarbital 100	d, 1-Thyroxine 120
1-Phenylephrine 100	Tolbutamide 100
(±)-Phenylpropanolamine 100	Triamterene 120
Prednisolone 150	Trifluoperazine 220
Prednisone 120	Trimethoprine 130
Promazine 120	Tronipramine 190
Promethazine 220	Trypamine 150
Propiomazine 220	d, 1-Tryptophan 170
d-Propoxyphene 100	d, 1-Tyrosine 250
Quinidine 100	Uric acid 230
Quinine 100	Verapamil 150
Ranitidine 200	Zomepirac 130
Salicylic acid 100	Sulfamethazine 150
Secoburhital 100	

Table-2: Concentration of amphetamine-related compounds showing a positive response approximately equivalent to the amphetamine cutoff set for the test.

Compound / Concentration in ng/ml

(±) 3,-1-Methylenedioxyamphetamine 500
p-Hydroxymethamphetamine 5000
Methoxyphenamine 50,000
(±) 3,4-Methylenedioxyamphetamine 50,000

3. **Accuracy:** An independent correlation study was performed using positive and negative urine specimens. Each urine specimen was tested with the *OneStep* Methamphetamine Card Test and a commercially available test (Syva®EMIT II). Positive results were confirmed by GC/MS. The results are summarized as follows:

Syva EMIT II Positive Syva EMIT II Negative

One step Positive	50	0
One step Negative	0	100

The relative sensitivity is 100%. The relative specificity is 100%. The data demonstrates the *OneStep* Methamphetamine Card Test is substantially equivalent to the commercially available test. The clinical significance of the two tests is comparable. 4. **Precision.** The precision was determined by replicate assays of three different patient urine samples with kits from three different production lots. Ten parallel assays were run from each of the three different lots on each urine sample. The resultant data indicated 100% precision for the duplicates within each lot and 100% precision between different lots.

REFERENCES

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