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One-Step Amphetamine Card Test

INTENDED USE

The One Step Amphetamine Test is a rapid qualitative, competitive binding, immunoassay for the determination of amphetamine in urine. Always justify preliminary positive and negative results with compelling clinical evidence and professional judgment. The test provides only preliminary data, which should be confirmed by other methods such as GC/MS.1-3

SUMMARY AND EXPLANATION

The One Step Amphetamine 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 amphetamine in urine samples with a high degree of sensitivity.

Amphetamine 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 use can result in higher tolerance levels, physiological dependency, and may lead to substance abuse.

Both *D* and *L* forms are controlled substances. The legally allowable level for amphetamine is set at 500 ng/ml in urine using the GC/MS detection method (1000 ng/ml for the immunoassay) by the U.S. National Institute on Drug Abuse.5

PRINCIPLE OF THE TEST

The One-Step Amphetamine 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 1000 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 Cassette
2. Dropper
3. Urine Cups
4. Test Instructions.

MATERIALS REQUIRED, BUT NOT PROVIDED

1. Clock or timer.
2. Sample collection and testing containers.

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 – 28oC). Do not freeze. Refer to the expiration date for stability.

SAMPLE COLLECTION AND PREPARATION

Collect a urine sample in a 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).

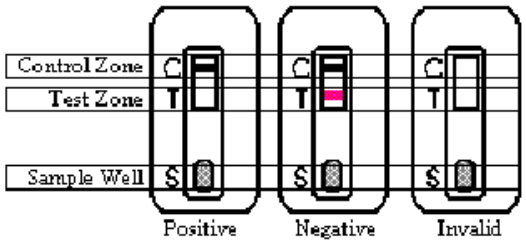
Bring frozen or refrigerated samples to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

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



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 amphetamine level is at or above the detection sensitivity of 1000 ng/ml.

Negative: Two horizontal rose-pink color band appear. one in the control zone “C” and one in the test zone “T”. This is a negative result and indicates the amphetamine level is below the detection sensitivity of 1000 ng/ml.

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 OF THE PROCEDURE

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.
3. The testis 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.

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PERFORMANCE CHARACTERISTICS

Sensitivity: The One Step Amphetamine Test detects amphetamine and the major metabolites of amphetamine in urine at concentrations equal to or greater than 1000 ng/ml, which is much lower than the normally found in the urine of regular users of amphetamine.

Specificity: A study was conducted with the One Step Amphetamine Test to determine the cross-reactivity of non-amphetamine 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 amphetamine-related compounds with the test. Substances listed in Table 2 produced results approximately equivalent to the cutoff level for amphetamine.

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

Compound / Concentration in ug/ml	
Acerophenaddin 100	Guatacol Glyceryl
Acetophenendin 100	Ether Carbonate 220
N-Acetylprocainamide 200	Glucuronic acid 200
Acetylsalicylic acid 300	Glutethimide 100
Amitryptyline 100	5-Hydoxytryplamine 100
Amohurhtal 100	Hippuric acid 200
Amaxicillin 130	Hydralazine 100
1-Amphetamine 100	Hydrochlorothiazide 100
Apomorphine 100	Hydrocodone 100
ASP-PHE Methyl Ester 100	Hydrocortisone 130
Airopine 100	Hydromorphone 100
Bercilic Acid 300	()-Hydroxyhippuric acid 140
Benznoic Acid 280	3-Hydroxyryramine 160
Benzoylegonine 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
(-) Collnine 100	Methaqualone 100
Creatinine 190	(S)-6-methoxy-a-methyl-
Deoxycorticosterone 170	2-naphthaleneacetic acid 250
Dextromethorphan 100	Methylphenidate 100
Diazepam 100	Methyprylon 100
Dicloferiac 100	Morphine-3- -D- glucuronide 100
Diflunisal 100	Nalidixic acid 130
Digoxin 150	Nalorphine 100
Diphenhydramine 200	Naloxone 100
4-Dimethylamoantipyrine 100	Naltrexone 100
Daxylamine 100	Niacinamide 170
(+) Ephedrine 130	Nifedipine 140
(+) Ephedrine 160	Norcodeine 100
d-y-Ephedrine 290	Norethindrone 100
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	

Table-1 (continued)

Oxymetazoline 100	Sulfamethazine 150
Papaverine 120	Sulindac 120
Penicillin-G 120	Temazepam 100
Pentazocaine 100	Tetracycline 200
Perphenazine 140	Tetrahydrocortisone 100
Phendimetrazine 100	Tetrahydrozoime 100
Phenelzine 350	Thebaine 100
Phenobarbital 100	Thlamine 120
1-Phenylephrine 100	Thioridazine 110
(±)-Phenylpropanolamine 100	d, 1-Thyroxine 120
Prednisolone 150	Tolbutamide 100
Prednisone 120	Triamiterene 120
Promazine 120	Trifluoperazine 220
Promethazine 220	Trimethoprine 130
Propiomazine 220	Tronipramine 190
d-Propoxyphene 100	Trypiamine 150
Quinidine 100	d, 1-Tryptophan 170
Quinine 100	d, 1-Tyrosine 250
Ranitidine 200	Uric acid 230
Salicylic acid 100	Verapamil 150
Secoburhital 100	Zomepirac 130

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
D-L-Amphetamine 1,000
(±) 3,-1-Methylenedioxyamphetamine 1,000
(±) Phenylpropanolamine 50,000
-Penylthylamine 90,000
Thyramine 100,000
D-,L-Methamphetamine 100,000

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

	Syva EMIT II Positive	Syva EMIT II Negative
Positive	35	0
Negative	0	185

The relative sensitivity is 100%. The relative specificity is 100%. The data demonstrates the OneStep Amphetamine Test is substantially equivalent to the commercially available test. The clinical significance of the two tests is comparable.

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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4. Dasgupta, A., Saldana, S., Kinnaman, G., Smith, M., Johansen, K., Clin. Chem., 39: 104-108 (1993).
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