

HEALTH-CHEM DIAGNOSTICS, LLC

3341 S.W. 15th Street – Pompano Beach, FL 33069 - USA – Phone: (954) 979-3845 – Fax: (954) 979-7997 Website:
www.healthchemdiagnostics.com

ONE STEP DRUGS OF ABUSE TEST STRIP - AMPHETAMINE™

NAME AND INTENDED USE

The HCD's **One Step Drugs of Abuse Test Strip - Amphetamine™** is a rapid, qualitative, competitive binding immunoassay for the determination of Amphetamine in urine in a convenient One Step strip test format. This test is not intended to monitor drug levels, but only to screen urine samples for the presence of amphetamines. Both the testing and the results of the testing are intended to be used by medical and legal professionals only. The test should not be used without appropriate supervision. The **One Step Drugs of Abuse Test Strip - Amphetamine™** assay is not intended for Over The Counter (OTC) sale to lay persons.

INTENDED USE

The **One Step Drugs of Abuse Test Strip - Amphetamine™** test is a rapid, qualitative, competitive binding immunoassay for the determination of amphetamine in urine. The test provides only screening data which should be confirmed by other methods such as gas chromatography/mass spectroscopy (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated⁶. The **One Step Drugs of Abuse Test Strip - Amphetamine™** assay is not intended to monitor drug levels, but only to screen urines for the presence of amphetamine and its metabolites.

EXPLANATION OF THE TEST

The method employs unique polyclonal antibodies to selectively identify amphetamine in test samples with a high degree of sensitivity. Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being⁴. Chronic doses of amphetamine could develop tolerances and physiological dependency and lead to its abuse. Both d(+) and l(-) forms of the isomers are controlled substances, and the legally allowable level for amphetamine is set at 500 ng/ml of urine by the National Institute on Drug Abuse⁵.

The **One Step Drugs of Abuse Test Strip - Amphetamine™** kit is an easy, fast, visually read competitive binding immunoassay method for the screening of urine for the presence of amphetamine without the need for instrumentation.

PRINCIPLE OF THE PROCEDURE

The **One Step Drugs of Abuse Test Strip - Amphetamine™** test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with the immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 500 ng/ml which is suggested for the immunoassay method. Unbound dye conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test line and control area.

A **POSITIVE** specimen produces only one color band in the control

area.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or timer.
3. 13 x 100mm test tube.

WARNINGS AND PRECAUTIONS

1. For **in vitro** diagnostic use only.
2. For professional medical and legal use only.
3. Avoid cross contamination of urine samples by using a new urine specimen cup for each sample.
4. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch.
5. Urine specimens may be infectious. Upon completion of all testing dispose of residual urine in a medically approved manner.
6. Properly handle and dispose of all used reaction devices in an approved biohazard container.

STORAGE AND STABILITY

The reagents supplied can be stored under refrigeration (2°-8°C)(35° - 46°F) **[DO NOT FREEZE]** or at room temperature (18° - 30°C)(64° - 86°F) and will be stable for 12 months.

SAMPLE COLLECTION AND PREPARATION

Urine (1.0 ml) - The sample must be collected in a clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C) and stored up to 48 hours, or frozen (-20°C or colder) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle so that clear aliquots can be obtained for testing.

ASSAY PROCEDURE

1. Remove **One Step Drugs of Abuse Test Strip - Amphetamine™** kit from its protective foil wrapper by tearing along the notch.
2. Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place into the urine and simultaneously start timing. Make sure only the end with the arrow pointing down is placed into the urine specimen. The urine level should not be higher than the maximum fill line indicated on the strip.
3. Read the results after 3 minutes. Test results should not be interpreted after 5 minutes.

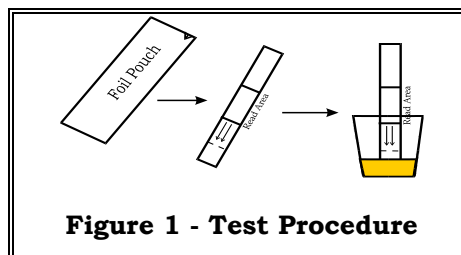


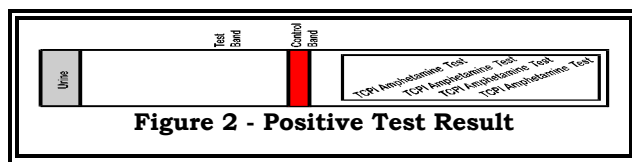
Figure 1 - Test Procedure

PERFORMANCE CHARACTERISTICS

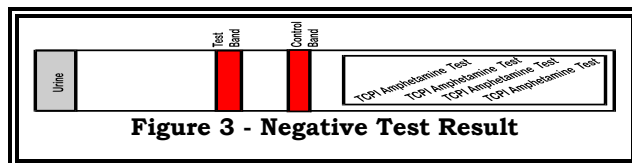
NOTES:

1. Refrigerated strips should be allowed to come to room temperature before opening the pouch.

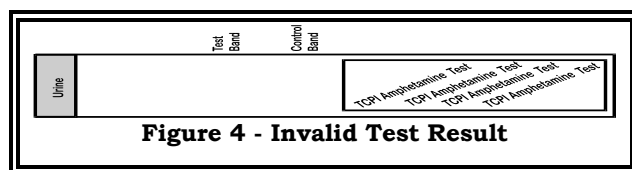
READING THE TEST RESULTS



1. **POSITIVE:** One magenta band appears on the control region. No visible band on the test region (lower portion of the read area). This is an indication that the amphetamine level is above the detection sensitivity level of 500 ng/ml of urine.



2. **NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the amphetamine level is below the detection sensitivity level of 500 ng/ml of urine.



3. **INVALID:** If there are no distinct color bands in both the upper and lower portions of the read area, (lower portion of the strip), or no band in the control region (upper portion of the read area), then the test results are invalid. It is recommended that the specimen be retested.

QUALITY CONTROL

Each reaction strip has its own built-in quality control indicator. If after performing the test no line is visible on the strip, the strip may have been placed into the tube incorrectly or the test device may have deteriorated. The assay will have to be repeated using a new **One Step Drugs of Abuse Test Strip - Amphetamine™**. Re-read the instructions carefully or call for assistance (800-482-2907).

Good laboratory practice recommends the use of control material to test each product shipment or whenever it is necessary to validate reagent performance and reliability. Commercial controls from BioRad, Uro-Qual Abutrol, Utak, and Alltech are available for validation of the device functionality. NIDA recommended guidelines for drugs of abuse screening indicate that controls should contain the drug of abuse analyte at levels at least 20% above the NIDA cut off values.

AFTER TESTING

Urine specimens may be infectious. Properly handle and dispose of all used reaction devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after completion of all testing including the confirmatory testing. Sample disposal may be controlled by legal chain of custody considerations.

Sensitivity:

The **One Step Drugs of Abuse Test Strip - Amphetamine™** test has been designed for the detection of amphetamine in urine at the detection sensitivity of 500 ng/ml which is suggested for the immunoassay method. Upon completion of the developmental phase **One Step Drugs of Abuse Test Strip - Amphetamine™** test was tested against SIA™ and GC/MS using 260 individual urine specimens (See Table 1). Based upon those data the sensitivity of the test was calculated to be 139/140 or 0.9929.

Specificity:

HCD's **One Step Drugs of Abuse Test Strip - Amphetamine™** test can specifically detect both d(+) and l(-) forms of amphetamine and a (±) mixture. Based upon the data presented in Table 1 the specificity was calculated to be 120/120 or 1.00.

Table 1 - Results of In House Testing

Reference	TCPI (+)	TCPI (-)	Row Totals
(+)	139	1	140
(-)	0	120	120
Col. Totals	139	121	260

Table 2 - Compounds which produce a positive reaction

Compound	Level or Concentration
d-Amphetamine	1 µg/ml
d, l-Amphetamine	2 µg/ml
3,4-Methylenedioxyamphetamine	1 µg/ml
Phentermine	1 µg/ml
Ephedrine	10µg/ml

Table 3 - Non-Interfering substances at 10 µg/ml levels

Substance	Reaction
Cannabidiol	0
± Deoxyephedrine	0
+ Methamphetamine	0
- Deoxyephedrine	0
Phencyclidine	0
Phenobarbital	0
Morphine	0

Table 4- Compounds which produce no reaction

Acetaminophen	Morphine Sulfate
Acetylsalicylic acid	Methylphenidate
Ampicillin	Methadone
Benzoic Acid	Methaqualone
Benzoyllecgonine HCl	Oxazepam
Caffeine	Oxycodone
Chlorpheniramine	Propranolol
Chlorpromazine HCl	Phencyclidine
Cimetidine	d-Propoxyphene
Codeine	Hydrochlorothiazide
Dextromethorphan	Phenylpropanolamine
Ecgonine HCl	Pendimethazine
Ecgonine Methyl Ester	Phentobarbital
Hydrocodone	Penicillin G
Hydromorphone	1-Phenylephrine
Indomethacin	Quinine
Ketoprofen	Ranitidine
Levorphanol	Tryptophan
Sodium Salicylate	Δ -9-THC
Meperidine	11-nor- Δ -9-carboxy-THC
Morphine Glucuronide	

BIBLIOGRAPHY

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5. Department of Health and Human Services, Fed. Regist., 53(69): 11970-89 (1988).
6. FDA Guidance for labeling Urine Drugs of Abuse Screening Testing, Kshitij Mohan, 7/21/1987.

Manufactured in the USA by:

**HEALTH-CHEM DIAGNOSTICS LLC,
3341 SW 15th STREET, POMPANO BEACH, FL - USA**

www.healthchemdiagnostics.com

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