

# HEALTH-CHEM DIAGNOSTICS, LLC

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## ONE STEP DRUGS OF ABUSE TEST STRIP - METHAMPHETAMINE™

### NAME AND INTENDED USE

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** is a rapid, qualitative, competitive binding immunoassay for the determination of Methamphetamine in urine in a convenient one step strip test format. This test is not intended to monitor drug levels, but only to screen urines for the presence of Methamphetamine. Both the testing and results 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 - Methamphetamine™** assay is not intended for Over-The-Counter (OTC) sale to lay persons.

### INTENDED USE

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** assay is a rapid, qualitative, competitive binding immunoassay for the determination of Methamphetamine in urine at the 500 ng/ml NIDA cutoff level. The test provides only preliminary data which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated<sup>1</sup>. The **One Step Drugs of Abuse Test Strip - Methamphetamine™** is not intended to monitor drug levels, but only to screen urines for the presence of methamphetamine and its metabolites.

### EXPLANATION OF THE TEST

The method employs unique polyclonal antibodies to selectively identify Methamphetamine in test samples with a high degree of sensitivity and specificity. Methamphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being<sup>2</sup>. Large doses of Methamphetamine could develop tolerances and physiological dependency and lead to its abuse. Both d (Δ) and l forms of the isomers are controlled substances, and the allowable level for Methamphetamine is set at 500 ng/ml in urine by the National Institute on Drug Abuse<sup>3</sup>.

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** kit is an easy, fast, and visually read competitive binding immunoassay method for screening without the need for instrumentation to arrive at a determination.

### PRINCIPLE OF THE PROCEDURE

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** 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 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. There is no meaning attributed to the line color, its intensity, or its size

### REAGENTS

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** 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. The method employs a unique mixture of monoclonal (mouse) and polyclonal (rabbit) antibodies to selectively identify Methamphetamine in the test samples. A colloidal gold conjugate is used to visualize the immunological reaction.

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers.
2. Clock or timer.
3. 13 x 100mm Test Tube.

### WARNINGS AND PRECAUTIONS

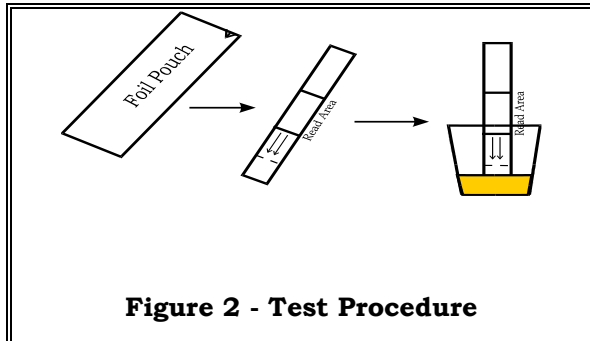
1. For **in vitro** diagnostic use only.
2. For professional medical and legal use only.
3. Do not use the test strip beyond the expiration date imprinted on the outside of the foil pouch and do not use if foil pouch is broken.
4. Use a new specimen container and dropper for each test to avoid cross-contamination of urine samples.
5. Urine specimens may be infectious. Upon completion of all testing dispose of residual urine in a medically approved manner. 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)(36° - 46°F) **[DO NOT FREEZE]** or at room temperature (18° - 30°C)(65° - 85°F) and will be stable until the expiration date.

## 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

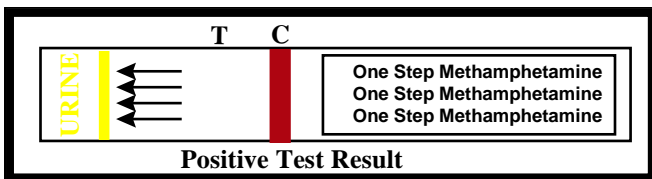
1. Remove the **One Step Drugs of Abuse Test Strip - Methamphetamine™** device from its protective foil wrapper by tearing at the notch.
2. Add 1 ml of urine to be tested to a 13 x 100mm test tube. Holding the strip in a vertical position, place it into the urine and simultaneously start timing. Make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

### NOTES:

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

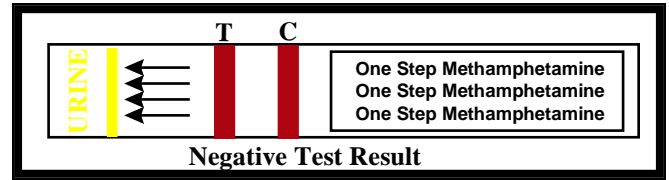
## READING THE TEST RESULTS

**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 Methamphetamine level is above the detection cutoff level of 500 ng/ml. There is no meaning attributed to the line color, its intensity, or its size

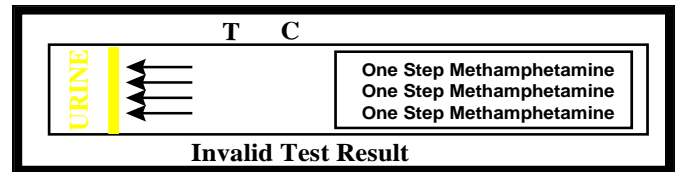


2. **NEGATIVE:** In addition to the control band, a magenta band also appears on the test region (lower portion of the read area). If this is the case, the Methamphetamine level

is below the detection cutoff level of 500 ng/ml. There is no meaning attributed to the line color, its intensity, or its size.



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

1. 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 strip may have deteriorated. The assay will have to be repeated using a new **One Step Drugs of Abuse Test Strip - Methamphetamine™**.

2. 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 cutoff 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.

## PERFORMANCE CHARACTERISTICS

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** has been designed for the detection of methamphetamine in urine at the detection cutoff of 500 ng/ml which is suggested for the immunoassay method. Upon completion of the developmental phase The **One Step Drugs of Abuse Test Strip - Methamphetamine™** was tested against SIA™ (screen) and GC/MS (reference) on 280 individual urine samples. The results on those 280 samples were identical for all three methods (SIA, GC/MS, & **One Step Drugs of Abuse Test Strip - Methamphetamine™**). Subsequently, a clinical trial of 300 samples was run and statistically evaluated before combining the data with the in-house results. The combined data are presented in Table 1 below.

**Table 1 - Results of All Clinical Testing**

GC/MS	One Step (+)	One Step (-)	Row Totals
(+)	270	0	270
(-)	16	294	310
<b>Col. Totals</b>	<b>286</b>	<b>294</b>	<b>580</b>

**Sensitivity:**

Based on the data collected in this study and presented in Table 1 above, the sensitivity was calculated to be 270/270 or 100%.

**Specificity:**

The **One Step Drugs of Abuse Test Strip - Methamphetamine™** can specifically detect both d (Δ) and l forms of methamphetamine and a mixture. The test has proven positive with 1.0 µg/ml or greater concentrations of both (+)Methamphetamine and Methylenedioxymethamphetamine. Using the data presented in Table 1 the specificity was calculated to be 294/310 or 94.84%.

**Accuracy:**

Based on the data presented in Table 1, the accuracy of the method in this study was determined to be 564/580 or 97.24%.

**Table 2 - Within Lot Reproducibility**

Drug Level ng/ml	N	Expected	Found	% Correct
0	15	Negative	Negative	100%
200	15	Negative	Negative	100%
375	15	Negative	Negative	93.33%
500	15	Positive	Positive	100%
624	15	Positive	Positive	100%
1000	15	Positive	Positive	100%

**Table 3 - Lot to Lot Reproducibility**

Drug Level ng/ml	N	Lot A	Lot B	Lot C
0	15	100%	100%	100%
200	15	100%	100%	100%
375	15	93%	87%	100%
500	15	100%	100%	100%
624	15	100%	100%	100%
1000	15	100%	100%	100%

Related compounds giving cross-reactivities at very high levels are as follows:

**Table 4 - Compounds That Will Produce A Positive Result**

Compound	Level or Concentration
(+) Methamphetamine	1 µg/ml
(±) 3,4-Methylenedioxymethamphetamine	1 µg/ml
d-Amphetamine	5 µg/ml
d, 1-Amphetamine	10 µg/ml
(±)3,4-Methylenedioxyamphetamine	10 µg/ml
Pseudoephedrine	10 µg/ml
Ephedrine	25 µg/ml

There is no interference by the following substances at a 10 mg/ml concentration in urine:

**Table 5 - Compounds Which Produce No Reaction**

Acetaminophen	Δ-9-THC
Acetylsalicylic Acid	11-nor-Δ-9-carboxy-THC-9-COOH
Amikacin	Meperidine
Amitriptyline	Methylphenidate
Ampicillin	Metadone
Arterenol	Methaqualone
Aspartame	Morphine Glucuronide
Atropine Sulfate	Morphine Sulfate
Benzoic Acid	Oxazepam
Benzoyllecgonine	Oxycodone
HCl	
Caffeine	Pendimethazine
Chlorpromazine HCl	Penicillin G
Chlorpheniramine	Pentobarbital
Cimetidine	d-Propoxyphene-Hydrochlorothiazide
	Propranolol
Codeine	Phencyclidine
Deoxyephedrine	Phenobarbital
Dextromethorphan	Phentermine
Diazepam	Phenylpropanolamine
Diethylpropion	L-Phenylephrine
Diphenylhydantoin	Quinine
Doxylamine	Ranitidine
Ecgonine HCl	Sodium Salicylate
Ecgonine Methyl Ester	
Glucose	Tryptophan
Histamine	Tetracycline
Hydrocodone	Tetrahydrozoline
Hydromorphone	Theophylline
Indomethacin	Thioridazine
Ketoprofen	Trifluoperazine
Levorphanol	

**Accuracy of Method based upon Combined Data:**

Based on the data presented in Table 1 the accuracy of the method in this study was determined to be 564/580 or 97.24%.

**LIMITATIONS OF THE TEST**

1. This product is designed to be used for the detection of Methamphetamine in human urine only.
2. Although the **One Step Drugs of Abuse Test Strip - Methamphetamine™** is very accurate (97.24%) in detecting the urine Methamphetamine level, there is a possibility of false results due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, e.g. technical or procedure errors associated with the testing.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative Methamphetamine levels in urine.
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.

## **BIBLIOGRAPHY**

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Manufactured in the USA by:

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