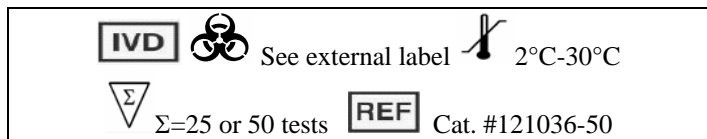


# CORTEZ DIAGNOSTICS, INC.

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## OneStep Methamphetamine InstaStrip

Catalog No. 121036-50 (50 tests)

### INTENDED USE

Cortez Diagnostic, Inc.'s OneStep Methamphetamine InstaStrip assay is a rapid, qualitative, competitive binding immunoassay for the determination of methamphetamine and its metabolites in urine at or above the cutoff level of 1000 ng/ml. OneStep Methamphetamine InstaStrip is not intended to monitor drug levels, but only to screen urines for the presence of methamphetamine and its metabolites.

*Note: 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.*

### SUMMARY AND EXPLANATION OF THE TEST

The OneStep Methamphetamine InstaStrip kit is an easy, fast, and visually-read competitive binding immunoassay method for screening without the need for instrumentation to arrive at a determination. The method employs unique polyclonal antibodies to selectively identify Methamphetamine and its metabolites in test samples with a high degree of sensitivity. Methamphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling well being<sup>2</sup>. Large doses of methamphetamine could develop tolerances and physiological dependency and lead to its abuse. Both Δ and L forms of the isomers are controlled substances, and the mandated allowable level for methamphetamine is set at 1000 ng/ml in urine by the confirmatory GC/MS method as specified by the National Institute on Drug Abuse (NIDA)<sup>3</sup>.

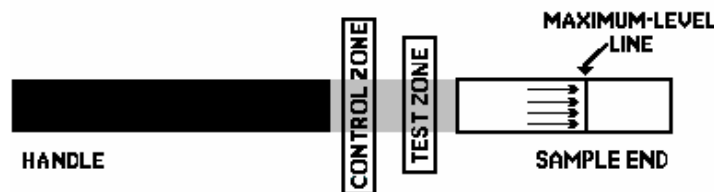
### PRINCIPLE OF THE TEST

The OneStep Methamphetamine InstaStrip 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 for limited antibody sites. As the test sample flows up through the absorbent device, the free drug in the specimen competes with immobilized antigen conjugate in the test zone by binding to the antibody-dye conjugate forming an antibody-antigen complex and

preventing the formation of a rose-pink color band when the drug is at or above the detection level of 1000 ng/ml.

In the case where free drug in the sample is below the detection level of 1000 ng/ml, antibody-dye conjugate is free to bind to the immobilized antigen in the test zone, producing a rose-pink color band. Furthermore, unbound dye conjugate binds to the reagent in the control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

A **NEGATIVE** specimen produces two distinct color bands in both the test zone and control zone. A **POSITIVE** specimen produces only one color band in the control zone.



### REAGENTS AND MATERIALS PROVIDED

1. Test Dipstick. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for goat anti-mouse IgG antibody. Test zone: contains amphetamine bovine protein antigen conjugates. Control zone: contains goat anti-mouse IgG antibody.
2. Test Instructions

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Urine collection container

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic and forensic use only.
2. Do not use the test strip beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in the biohazard container.
4. Visually inspect the foil package to insure it is intact. If the package is not intact, discard the device.

### STORAGE AND STABILITY

Store test kit below 28°C; do not freeze. Refer to the expiration date for stability.

### SAMPLE COLLECTION AND PREPARATION

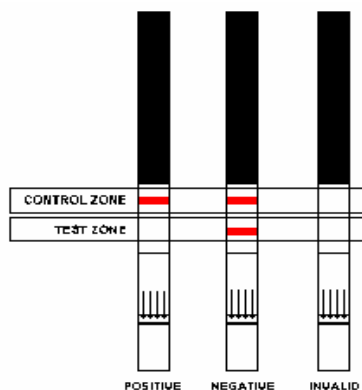
The sample must be collected in clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2°-8°C) and stored up to 48 hours, or frozen (-20°C or below) prior to assaying. If samples are refrigerated or frozen they should be allowed to come to room 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.

### TEST PROCEDURE

1. Bring test components and urine sample to room temperature (15°-28°C).

- Dip the strip into the urine specimen with the arrow pointing toward the sample. The sample arrow should not be higher than the arrow pointed maximum line.
  - Hold the strip in the urine until a reddish color appears at the test area (approximately 20 seconds).
  - Withdraw the strip and place it face up on a clean, non-absorptive surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line.
- Do not interpret results after 5 minutes.**

## INTERPRETATION OF RESULTS



- Positive.** A *rose-pink* color band appears in the Control Zone but not in the Test Zone. This is a positive result and indicates the methamphetamine level is at or above the detection sensitivity of 1000 ng/ml.
- Negative.** Two horizontal *rose-pink* color bands appear, one in the Control Zone and one in the Test Zone. This is a negative result and indicates the methamphetamine level is below the detection sensitivity of 1000 ng/ml.
- Invalid.** No *rose-pink* bands appear, or a band appears in the Test Zone, but not in the Control Zone. An invalid result may be due to improper testing procedures or deterioration of the test kit components. Repeat the assay sequence by using a new device.

## 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.

**Note:** There is no meaning attributed to line color intensity or width.

## LIMITATIONS OF THE TEST

- This product is designed for use with human urine only.
- Although the test is very accurate, there is a possibility that false results will occur due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, e.g. technical or procedural errors associated with the testing.
- The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.
- 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 InstaStrip detects methamphetamine and the major metabolites of methamphetamine in urine at concentrations equal to or greater than 1000 ng/ml, which is suggested by NIDA for the immunoassay method.

### 2. SPECIFICITY.

Interference Testing.

The OneStep test performance at negative and positive (cutoff) may not be affected when pH and Specific Gravity ranges of urine are at 4.0 to 9.0 and 1.005 to 1.035.

Each listed substance that is commonly found in the urine was evaluated and indicated negative result at the concentration listed below (by adding the compound in the negative urine):

Glucose: 2000 mg/dl  
Human hemoglobin: 10 mg/dl  
Uric acid: 10 mg/dl  
Human albumin: 2000 mg/dl  
Urea: 4000 mg/dl

A study was conducted with the OneStep Methamphetamine InstaStrip 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 I.**

A separate study was conducted to determine the cross-reactivity of methamphetamine-related compounds with the test.

**Table-I: Compounds tested and found not to cross-react with the test at a 10 mg/ml concentration in urine:**

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

**Table-II: Concentration of methamphetamine-related compounds showing a positive response approximately equivalent to the methamphetamine cut off set for the test.**

Compound	Concentration in ng/ml
d-Amphetamine	50,000
$\Delta$ -l-amphetamine	10,000
(±) 3,4-Methylenedioxymethamphetamine (MDMA)	500
(±) 3,4-Methylenedioxyamphetamine (MDA)	50,000
Pseudoephedrine	1,000
Ephedrine	25,000

**Table II** produced results approximately equivalent to the cutoff level for methamphetamine.

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

	<u>Syva EMIT II Positive</u>	<u>Syva EMIT II Negative</u>
OneStep Positive	193	0
OneStep Negative	6	256

When compared to Emit II, the relative sensitivity was 97.7%. The relative specificity was 100%. The concordance of the combined data was 98.68%.

4. **Precision.** The precision was determined by replicate assays of three different patient urine samples with kits from three different production lots. The resultant data indicated 100% precision for the duplicates within each lot and no appreciable inter lot variation when testing both positive and negative spiked samples across three (3) different lots of devices.

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