

**OneStep  
 Amphetamine  
 RapiDip™ InstaTest**

**REF 121021-1-44**

**IVD**  See external Label  2-30°C   $\Sigma=1$  Test

<b>Sensitivity</b>	<b>1000 ng/ml</b>
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*A rapid test for the qualitative detection of Amphetamine in human urine, and for medical and other professional in vitro diagnostic use only.*

**INTENDED USE**

The Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest is a rapid chromatographic immunoassay for the detection of Amphetamine in human urine at a cut-off concentration of 1,000 ng/ml. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

**SUMMARY AND EXPLANATION**

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines-epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and

cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Amphetamine in urine. The AMP Rapid Test Dipstick (Urine) yields a positive result when Amphetamines in urine exceed 1,000 ng/mL.

**TEST PRINCIPLE**

The Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest is a rapid chromatographic immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Amphetamine, if present in the urine specimen below 1,000 ng/mL, will not saturate the binding sites of the antibody coated particles in the test. The antibody coated particles will then be captured by immobilized Amphetamine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Amphetamine level exceeds 1,000 ng/mL because it will saturate all the binding sites of anti-Amphetamine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**SPECIMEN COLLECTION AND PREPARATION**

**Urine Assay**

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing

**Specimen Storage**

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

**MATERIALS AND COMPONENTS**

**Materials provided with the test kits**

- Test dipstick: It contains mouse monoclonal anti-Amphetamine antibody-coupled particles and Amphetamine-protein conjugate. A goat antibody is employed in the control line system.
- Package insert

**Materials required but not provided**

- Specimen collection container
- Timer

**PRECAUTION**

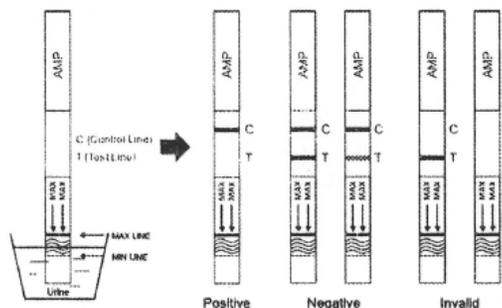
- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

**ASSAY PROCEDURE**

**Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the test dipstick from the sealed pouch and use it within one hour.
2. With arrows pointing toward the urine specimen, immerse the test dipstick vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the Test Dipstick when immersing the strip. See the illustration below.

3. Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



## RESULTS

(Please refer to the illustration above)

**NEGATIVE: \*Two line appear.** One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Amphetamine concentration is below the detectable level (1,000 ng/mL).

\*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE:** One colored line appear in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Amphetamine concentration exceeds the detectable level (1,000 ng/mL).

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

## PERFORMANCE CHARACTERISTICS

### Accuracy

A side by side comparison was conducted using the Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest and a

commercially available AMP rapid test. Testing was performed on 100 clinical specimens previously collected from subjects present for Drug Screen. The following results were tabulated.

Method	Other AMP Test		Total Results	
	Results	Positive		Negative
OneStep AMP RapiDip™	Positive	33	0	33
InstaTest	Negative	0	67	67
<b>Total Results</b>		33	67	100
<b>% Agreement</b>		>99.9%	>99.9%	>99.9%

A side by side comparison was conducted using the Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest and GC/MS at the cut-off of 1,000ng/mL. Testing was performed on 250 clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method	GC MS		Total Results	
	Results	Positive		Negative
OneStep AMP RapiDip™	Positive	103	3	106
InstaTest	Negative	2	142	144
<b>Total Results</b>		105	145	250
<b>% Agreement</b>		>98.1%	>97.9%	>98.0%

### Analytical Sensitivity

A drug-free urine pool was spiked with Amphetamine at the following concentrations: 0 ng/mL, 500 ng/mL, 750ng/mL, 1000ng/mL, 1250 ng/mL, 1500 ng/mL and 3000 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below.

Amphetamine Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
500	-50%	30	30	0
750	-25%	30	26	4
1000	Cut-off	30	15	15
1,250	+25%	30	3	27
1,500	+50%	30	0	30
3,000	3X	30	0	30

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest at 5 minutes.

Compound	Concentration (ng/mL)
D,L-Amphetamine sulfate	300
L-Amphetamine	25,000
(+/-) 3,4-Methylenedioxyamphetamine	500
Phentermine	800
Maprotiline	50,000
Methoxyphenamine	6,000
D-Amphetamine	1,000

### Precision

A study was conducted at three hospitals by layperons using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, according to GC/MS, no Amphetamine, 250% Amphetamine above and below the cut-off, and 50% Amphetamine above and below the 1,000 ng/ml cut-off was provided to each site. The results are given below:

Amphetamine Concentration (ng/mL)	N per site	Site A		Site B		Site C	
		+	+	+	+	+	+
0	10	10	0	10	0	10	0
500	10	10	0	10	0	10	0
100	10	9	1	8	2	9	1
1,250	10	1	9	2	8	2	8
1,500	10	0	10	0	10	0	10

### Effect of Urine Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 500 ng/ mL, and 1,500 ng/mL of Amphetamine. The Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

### Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with

Amphetamine to 500 ng/ml and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with the Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

### Gross-Reactivity

A study was conducted to determine the cross-activity of the test with compounds in either drug-free urine or Amphetamine positive urine. The following compounds show no cross-reactivity when tested with the Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest at a concentration of 100 ng/mL.

#### Non Cross-Reacting Compounds

4-Acetamidophenol	Ketoprofen
Acetophenetidin	Labetalol
N-Acetylprocainamide	Levorphanol
Acetylsalicylic acid	Loperamide
Aminopyrjino	Maprotiline
Amitypytline	Meperidine
Amobarbital	Meprobamate
Amoxicillin	Methadone
Ampicillin	D-Methamphetamine
L-Awrbic acid	L-Methamphetamine
Apoiorphine	Methoxyphenamine
Aspartame	3,4-Methylenedioxyethyl- amphetamine
Atropine	(+) 3,4-Methylenedioxy- methamphetamine
Benzilic acid	
Benzoic acid	
Benzoylcegonine	Methylphenidate
Benzphetamine	Morphine-3-β-D- glucuronide
Bilirubin	Nalidixic acid
(+/-)Bompheniramine	Naloxone
Catfeine	Oxolinic acid
Cannabidiol	Oxycodone
Cannabinol	Oxymetazotine
Chloialhydrate	Papaverine
Chloramphenicol	Penicillin-G
Chlordiazepoxide	Penicillin-G
Chlorothiazide	Pentazocine
(+/-) Chlorpheniramine	Pentobarbital
Chlorpomazine	Pelphenazine
Chlorquine	Phencyclidine
Cholesterol	Phenelzine

Clomipramine	Phenobarbital
Clonidioe	L-Phenylephrine
Cocaine hydrochloride	β -Phenylethlamine
Codeine	Phelylpropanolamine
Corlisne	Prednisolone
(-) Cotinine	Prednisone
Greatinine	Procaine
Deoxycorticosterone	Promazine
Dextromethorphan	Promethazine
Diazepam	D,L-Propranolol
Diclofenac	D.Propoxyphene
Diflunisal	D-Pseudoephedrine
Digoxin	Ouinidine
Diphenhydramine	Ouinine
Doxylamine	Ranitidine
Ecgonine hydrochloride	Salicylic acid
Ecgonine methylester	Secobarbital
(1R,2S)-(-)-Ephedrine	Serotonin
L-Ephedrine	(5-Hydroxytyramine)
(-)-ψ-Ephedrine	Sulfamethazine
Erythromycin	Sulindac
0-Estradiol	Temazepam
Estrone-3-sulfate	Tetracycline
Ethyl-p-aminobenzoate	Tetrahydrocotisone
Fenfluramine	3-Acetate
Fenoprofen	Tetrahydrocortisone
Furosemide	3--β-D-glucuronide
Gentisic acid	Tetrahydrozoline
Hemoglobin	Thebaine
Hydralazine	Thiamine
Hydrochlorothiazide	Thioridazine
Hydrocodone	Tolbutamine
Hydrocortisone	Triamterene
p-Hydroxyamphetamine	Trifluoperazine
O-Hydroxyhippuric acid	Trimethoprim
p-Hydroxynethamphetamine	Trimipramine
3-Hydroxytyramine	D, L-Tryptophan
Ibuprofen	Tyramine
Imipramine	D, L-Tyrosine
(+/-)-Isoproterenol	Uric acid
Isoxsuprine	Verapamil
Ketamine	Zomepirac

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS OF PROCEDURE

1. The Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.(1,2)
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

### EXPECTED VALUES

In this test, the negative result indicates that the Amphetamine concentration is below the detectable level of 1,000ng/ml. The positive result means the concentration of Amphetamine is above the level of 1000 ng/ml. The Cortez Diagnostics, Inc. OneStep AMP RapiDip™ InstaTest has a sensitivity of 1,000 ng/ml

**REFERENCE**

1. Baselt RC. Disoosition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA 1982;488
2. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA) Research Monograph 73, 1986

<p><b>ISO 13485</b> <b>ISO 9001</b></p>  <p> <b>Diagnostic Automation/ Cortez Diagnostics, Inc.</b> 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
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<b>EC</b> <b>REP</b>	<b>CEpartner4U, Esdoornlaan 13, 3951DB Maarn. The Netherlands.</b> <a href="http://www.cepartner4u.eu">www.cepartner4u.eu</a>
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