

# SureStep™ AMP 300 Amphetamine Test Device (Urine) Package Insert

## One Step

## English

A rapid, one step test for the qualitative detection of Amphetamine in human urine.  
For medical and other professional *in vitro* diagnostic use only.

### INTENDED USE

The AMP 300 One Step Amphetamine Test Device (Urine) is a lateral flow chromatographic immunoassay for the detection of Amphetamine in human urine at a cut-off concentration of 300 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

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 AMP 300 One Step Amphetamine Test Device (Urine) 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 Amphetamines in urine. The AMP 300 One Step Amphetamine Test Device (Urine) yields a positive result when Amphetamines in urine exceed 300 ng/mL. The suggested Amphetamine screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA) is 1,000 ng/mL.

### PRINCIPLE

The AMP 300 One Step Amphetamine Test Device (Urine) 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 300 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 300 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 because of drug competition, 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.

### REAGENTS

The test contains mouse monoclonal anti-Amphetamine antibody-coupled particles and Amphetamine-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- 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.

### STORAGE AND STABILITY

Store as packaged in the sealed pouches either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### 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 assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test devices
- Package insert

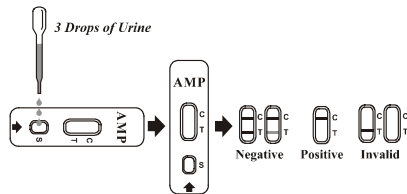
#### Materials Required But Not Provided

- Specimen collection container
- Timer

### DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer **3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**NEGATIVE:** \* **Two lines 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 (300 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 pink line.

**POSITIVE:** **One colored line appears 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 (300 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.

### 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 practice to confirm the test procedure and to verify proper test performance.

### LIMITATIONS

- The AMP 300 One Step Amphetamine Test Device (Urine) 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.<sup>1,2</sup>
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.

### PERFORMANCE CHARACTERISTICS

#### Accuracy

A side-by-side comparison was conducted using the AMP 300 One Step Amphetamine Test Device (Urine) and a leading commercially available AMP 300 rapid test. Testing was performed on 300 clinical specimens previously collected from subjects present for Drug Screen Testing. Ten percent of the specimens employed were either at -25% or +25% level of the cut-off concentration of 300 ng/mL Amphetamine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Other AMP 300 Rapid Test		Total Results
	Results	Negative	
AMP 300 One Step Test Device	Positive	127	127
	Negative	0	173
	<b>Total Results</b>	<b>127</b>	<b>173</b>
<b>% Agreement</b>	<b>&gt;99%</b>	<b>&gt;99%</b>	<b>&gt;99%</b>

When compared at 300 ng/mL cut-off with GC/MS, the following results were tabulated:

Method	GC/MS		Total Results
	Results	Negative	
AMP 300 One Step Test Device	Positive	125	127
	Negative	0	173
	<b>Total Results</b>	<b>125</b>	<b>175</b>
<b>% Agreement</b>	<b>&gt;99%</b>	<b>99%</b>	<b>99%</b>

#### Analytical Sensitivity

A drug-free urine pool was spiked with D-Amphetamine at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL and 450 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
150	-50%	30	30	0
225	-25%	30	25	5
300	Cut-off	30	16	14
375	+25%	30	4	26
450	+50%	30	0	30

#### Analytical Specificity

The following table lists compounds that are positively detected in urine by the AMP 300 One Step Amphetamine Test Device (Urine) at 5 minutes.

Compound	Concentration (ng/mL)	Compound	Concentration (ng/mL)
D-Amphetamine	300	β-Phenylethylamine	100,000
D,L-Amphetamine sulfate	390	Tyramine	100,000
L-Amphetamine	50,000	P-Hydroxynorephedrine	100,000
(±) 3,4-Methylenedioxymphetamine	1,560	(±/-) Phenylpropanolamine	100,000
p-Hydroxyamphetamine	1,560	p-Hydroxyamphetamine	100,000
DL-Norephedrine	100,000	(DL-Norephedrine HCL)	100,000

### Precision

A study was conducted at 3 physicians' offices by untrained operators 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, 25% Amphetamine above and below the cut-off, and 50% Amphetamine above and below the 300 ng/mL cut-off was provided to each site.

Amphetamine Concentration (ng/mL)	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
225	15	9	6	14	1	11	4
375	15	1	14	3	12	0	15
450	15	0	15	0	15	0	15

### Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 150 ng/mL and 450 ng/mL of Amphetamine. The AMP 300 One Step Amphetamine Test Device (Urine) 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 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with the AMP 300 One Step Amphetamine Test Device (Urine) in duplicate. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

### Cross-Reactivity

A study was conducted to determine the cross-reactivity 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 AMP 300 One Step Amphetamine Test Device (Urine) at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

4-Acetamidophenol	Hydrocotrisone	Phenelzine	5β-pregnane-3α, 17α, 21
Acetophenetidin	O-Hydroxyphenol	Phenobarbital	(Triol 20-one)
N-Acetylprocainamide	P-Hydroxymethamphetamine	Phentermine	L-Throxine
Acetylacetylic acid	3-Hydroxytyramine	L-Phenylephrine	EDDP
Aminopyrine	(Dopamine)	Prednisolone	L-Ephedrine
Amitypyline	Ibuprofen	Prednisone	EMDP
Amobarbital	Imipramine	Procaine	Fenfluramine
Ascorbic acid	Ironizalide	Quinidine	Methylpyron
Amoxycillin	(-)-Isoproterenol	Quinine	Nalorphine
Apomorphine	Isosuprine	Salicylic acid	Normorphine
Aspartame	Ketamine	Secobarbital	Oxymorphone
Atropine	Ketoprofen	5-Hydroxytyramine	Cyclobenzaprine
Benizile acid	Labeltol	(Serotonin)	Lithium cacbonate
Benzoic acid	Levorphanol	Sulfamethazine	Lidocaine
Benzydiazepam	Loperamide	Sulindac	Hydroxyzine
Benzphetamine	Hemoglobin	Temazepam	Guaiacal Glyceryl Ether
Bilirubin	Maprotiline	Tetracycline	-carbamate
Cannabidiol	Meprobamate	Tetrahydrocortison3acetate	Guaiacal Glyceryl Ether
Chloralhydrate	Methadone	Tetrahydrozoline	Amoxapine
Chloramphenicol	Chloramphenicol	Thebaine	(+/-)Chlorpheniramine
Chloridiazepoxide	Methamphetamine	Thiamine	Chlorpropricaine
Chlorothiazide	Methoxyphenamine	Thioridazine	R (-) Deprenyl HCL
Chlorpromazine	(+) 3,4-Methylenedioxy	(Cholpromazine)	Orphenadrine
Chlorquine	-Methamphetamine	DL-Tyrosine	Pheniramine
Cholesterol	Methylphenidate	Tolbutamide	4-Dimethylaminoantiprine
Clozapine	Morphine 3-β-D- Glucuronide	Triamterene	Riboflavin
Clonidine	Nalidixic acid	Trifluoperazine	Alpha-Naphthalenesacetic Acid
Cocaine hydrochloride	Naloxone	Trimeperidom	(+/-) Epinephrine
Codine	Naltrexone	Tryptamine	Trimethobenzamide
Cortisone	Naproxen	DL-Tryptophan	L-Methamphetamine
(-) Cotinine	Niaciamine	Tyramine	Hydromorphone
Creatinine	Nifedipine	Uric acid	(-) Deoxyephedrine
Deoxycorticosterone	Norendin	Verapamil	Ephedrine
Dextromethorphan	Norethindrone	Zomepirac	Phenothiazine
Diazepam	D-Norpropoxyphene	Acetamin	Acetone
Diclofenac	Noscapine	Caffeine	Albumine
Diffumisal	DL-Octopamine	(+/-) Chlorpheniramine	D (+) Glucose
Digoxin	Oxalic acid	Brompheniramine	Ethanol (Ethyl alcohol)
Diphenhydramine	Oxazepam	Ranitidine	Sodium chloride
Doxylamine	Oxoline acid	Cannabinol	Methaqualone
Egonine hydrochloride	Oxycodone	Morphine sulfate	Fanprazole
Egonine methylester	Oxymetazoline	Oxycartrine	Pemoline
(-) Ψ-Ephedrine	Promazine	Mephentermine	Cimetidine
Erythromycine	Promethazine	Trans2Phenylcyclopropylamine	Disopyramide
B-Estradiol	DL-Propranolol	(R, 2S)(-) Ephedrine	Lindane
Estrore 3 sulfate	D-Propoxyphene	(+) Ψ-Ephedrine	(Hexachlorocyclohexane)
Ethyl-p-aminobenzoate	(D-Pseudoephedrine)	Dicyclomine	Etidolate
Fenpropion	Papaverine	Trazodone	Kanamycin
Furosemide	Penicillin G	Nimesulide	Fluoxetine
Genitise acid	Pentazocine	Buspirone	Fentanyl
Hydrochlorazide	Hydrochlorazide	Hydrochlorazide	Cyclobarbital
Hydrocodone	Phenylclidine	Phenylclidine	Metoprolol
		Elavivny (Sustiva)	Cis-Tramadol

### BIBLIOGRAPHY

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

### Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #



**Innovacon, Inc.**  
4106 Sorrento Valley Boulevard  
San Diego, CA 92121, USA



**EC REP**  
MDSS GmbH  
Schiffgraben 41  
30175 Hannover, Germany

Number: 1155851301  
Effective Date: 2006-xx-xx