# ROJAN® AMP

## One Step
## Amphetamine Test Strip
## Package Insert

| REF: R-1106 | English |
|---|---|

*A rapid, one step test for the qualitative detection of Amphetamines in human urine.*

*For healthcare professionals including professionals at point of care sites.*

*For in vitro diagnostic use only.*

## INTENDED USE

The AMP One Step Amphetamine Test Strip is a lateral flow chromatographic immunoassay for the detection of Amphetamines in human urine.

**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 presecription (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 One Step Amphetamine Test Strip 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 One Step Amphetamine Test Strip yields a positive result when Amphetamines in urine exceed 1,000 ng/mL.

## PRINCIPLE

The AMP One Step Amphetamine Test Strip 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. Amphetamines, 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 strip. 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 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 strip contains mouse monoclonal anti-Amphetamine antibody-coupled particles and Amphetamine-protein conjugate. A goat antibody is employed in the control line system.

## PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip 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 strip should be discarded according to federal, state and local regulations.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strips 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 a 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

### Materials Provided

- Test strips
- Package insert

### Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

## DIRECTIONS FOR USE

**Allow the test strip, 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 strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10-15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

## INTERPRETATION OF RESULTS

(Please refer to the illustration below)

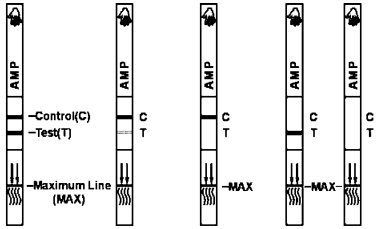
**NEGATIVE:* Two lines appear**. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the Amphetamine concentration is below the detectable level (1,000 ng/mL).

*** NOTE:** The shade of red in the test line region (T) will vary, but it should always be considered as negative whenever there is even a faint pink line.

**POSITIVE: One red line appears in the control region (C).** No line appears in the test 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 strip. If the problem persists, discontinue using the lot immediately and contact your local distributor.

**Test Results**




## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive 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

1. The AMP One Step Amphetamine Test Strip 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) are the preferred confirmatory methods.[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 or 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 cutoff level of the Test.
6. Test does not distinguish between drugs of abuse and certain medications.

## PERFORMANCE CHARACTERISTICS

### Accuracy

A side-by-side comparison was conducted using the AMP One Step Amphetamine Test Strip and a leading commercially available AMP rapid test. Testing was performed on 300 clinical specimens. Ten percent of the specimens employed were either at –25% or +25% level of the cut-off concentration of 1,000 ng/mL Amphetamine. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

| Method | | Other AMP Rapid Test | | Total Results |
|---|---|---|---|---|
| AMP One Step Test Strip | Results | Positive | Negative | |
| | Positive | 141 | 0 | 141 |
| | Negative | 5 | 154 | 159 |
| Total Results | | 146 | 154 | 300 |
| % Agreement with this commercial kit | | 97% | 100% | 98% |

When compared to GC/MS at the cut-off of 1,000 ng/mL, the following results were tabulated:

| Method | | GC/MS | | Total Results |
|---|---|---|---|---|
| AMP One Step Test Strip | Results | Positive | Negative | |
| | Positive | 132 | 9 | 141 |
| | Negative | 4 | 155 | 159 |
| Total Results | | 136 | 164 | 300 |
| % Agreement with GC/MS Analysis | | 97% | 95% | 96% |

Eighty (80) of these samples were also run using the AMP One Step Amphetamine Test Strip by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

### Analytical Sensitivity

A drug-free urine pool was spiked with Amphetamine at the following concentrations: 0 ng/mL, 500 ng/mL, 750 ng/mL, 1,000 ng/mL, 1,250 ng/mL and 1,500 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 Cutoff | n | Visual Result | |
|---|---|---|---|---|
| | | | Negative | Positive |
| 0 | 0% | 30 | 30 | 0 |
| 500 | -50% | 30 | 30 | 0 |
| 750 | -25% | 30 | 22 | 8 |
| 1,000 | Cutoff | 30 | 12 | 18 |
| 1,250 | +25% | 30 | 2 | 28 |
| 1,500 | +50% | 30 | 0 | 30 |

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the AMP One Step Amphetamine Test Strip at 5 minutes.

| Compound | Concentration (ng/mL) |
|---|---|
| D-Amphetamine | 1,000 |
| D,L-Amphetamine sulfate | 3,000 |
| L-Amphetamine | 50,000 |
| (+) 3,4-Methylenedioxyamphetamine | 2,000 |
| Phentermine | 3,000 |

### Precision

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Amphetamine, 25% 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 | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 500 | 15 | 15 | 0 | 15 | 0 | 14 | 1 |
| 750 | 15 | 13 | 2 | 11 | 4 | 11 | 4 |
| 1,250 | 15 | 6 | 9 | 4 | 11 | 4 | 11 |
| 1,500 | 15 | 2 | 13 | 1 | 14 | 1 | 14 |

### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges were spiked with 500 ng/mL and 1,500 ng/mL of Amphetamine respectively. The AMP One Step Amphetamine Test Strip was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

### Effect of the 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 AMP One Step Amphetamine Test Strip 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 Ampehtamine positive urine. The following compounds show no cross-reactivity when tested with the AMP One Step Amphetamine Test Strip at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

| | | |
|---|---|---|
| 4-Acetamidophenol | Estrone-3-sulfate | Oxolinic acid |
| Acetophenetidin | Ethyl-p-aminobenzoate | Oxycodone |
| N-Acetylprocainamide | Fenfluramine | Oxymetazoline |
| Acetylsalicylic acid | Fenoprofen | Papaverine |
| Aminopyrine | Furosemide | Penicillin-G |
| Amitryptyline | Gentisic acid | Pentazocine |
| Amobarbital | Hemoglobin | Pentobarbital |
| Amoxicillin | Hydralazine | Perphenazine |
| Ampicillin | Hydrochlorothiazide | Phencyclidine |
| Ascorbic acid | Hydrocodone | Phenelzine |
| Apomorphine | Hydrocortisone | Phenobarbital |
| Aspartame | p-Hydroxyamphetamine | L-Phenylephrine |
| Atropine | O-Hydroxyhippuric acid | β-Phenylethlamine |
| Benzilic acid | p-Hydroxy-methamphetamine | Phenylpropanolamine |
| Benzoic acid | | Prednisolone |
| Benzoylecgonine | 3-Hydroxytyramine | Prednisone |
| Benzphetamine | Ibuprofen | Procaine |
| Bilirubin | Imipramine | Promazine |
| Brompheniramine | (-) Isoproterenol | Promethazine |
| Caffeine | Isoxsuprine | D,L-Propanolol |
| Cannabidiol | Ketamine | D-Propoxyphene |
| Cannabinol | Ketoprofen | D-Pseudoephedrine |
| Chloralhydrate | Labetalol | Quinidine |
| Chloramphenicol | Levorphanol | Quinine |
| Chlordiazepoxide | Loperamide | Ranitidine |
| Chlorothiazide | Maprotiline | Salicylic acid |
| (±) Chlorpheniramine | Meperidine | Secobarbital |
| Chlorpromazine | Meprobamate | Serotonin (5-Hydroxytyramine) |
| Chlorquine | Methadone | Sulfamethazine |
| Cholesterol | D-methamphetamine | Sulindac |
| Clomipramine | (L)-methamphetamine | Temazepam |
| Clonidine | Methoxyphenamine | Tetracycline |
| Cocaine hydrochloride | 3,4-Methylenedioxyethyl-amphetamine | Tetrahydrocortisone, 3 Acetate |
| Codeine | (+) 3,4-Methylenedioxy-methamphetamine | Tetrahydrocortisone 3 (β-D glucuronide) |
| Cortisone | Methylphenidate | Tetrahydrozoline |
| (-) Cotinine | Morphine-3-β-D-glucuronide | Thebaine |
| Creatinine | Nalidixic acid | Thiamine |
| Deoxycorticosterone | Naloxone | Thioridazine |
| Dextromethorphan | Naltrexone | Tolbutamine |
| Diazepam | Naproxen | Triamterene |
| Diclofenac | Niacinamide | Trifluoperazine |
| Diflunisal | Nifedipine | Trimethoprim |
| Digoxin | Norcodein | Trimipramine |
| Diphenhydramine | Norethindrone | D, L-Tryptophan |
| Doxylamine | D-Norpropoxyphene | Tyramine |
| Ecgonine hydrochloride | Noscapine | D, L-Tyrosine |
| Ecgonine methylester | D,L-Octopamine | Uric acid |
| (1R,2S)-(-)-Ephedrine | Oxalic acid | Verapamil |
| L-Ephedrine | Oxazepam | Zomepirac |
| (-) Y Ephedrine | | |
| Erythromycin | | |
| β-Estradiol | | |

## BIBLIOGRAPHY


1. Baselt RC. Disposition 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


**Index of Symbols**

| | | | |
|---|---|---|---|
| Attention, see instructions for use | Tests per kit | Manufacturer | |
| For *in vitro* diagnostic use only | Use by | Do not reuse | |
| Store between 2-30°C | Lot Number | | |

ISO, CE, GMP


Rojan Azma

*Rojan Azma* mfg. Co.
No. 41, Golestan 4, Baharestan Industrial Estate, 5th km Karaj-Qazvin Highway, Tehran-Iran
Tel: +98-261-47 60 610
www.rojanazma.com