

# Amphetamine Urine Dipstick Test

AMPDS1000

## Name and Intended Use

The Amphetamine Urine Cassette Test qualitatively detects amphetamine in urine samples. The results obtained are of a preliminary nature and is for screening purposes only; positive results should be confirmed by way of a non-immunological method, such as gas chromatography mass spectrometry (GC/MS).

## Summary of Test

Amphetamine is a central nervous system stimulant similar to methamphetamine in chemical structure and physiological effects (methamphetamine is more potent). Amphetamine is present in urine in the form of derivatives, as well as some intact amphetamine 24-72 hours after dose. This is what denotes an amphetamine user.

## Principle of Procedure

The Amphetamine Urine Cassette Test is an immunochromatography device based on the principle of competitive immunoassay. The plastic cassette holds the chromatographic immunoassay strip and provides access (well S) of urine sample to the assay strip and a test result window. The nitrocellulose membrane of the chromatographic immunoassay strip is immobilized with amphetamine-protein conjugate on the test zone (see Figure 1). Antibodies against amphetamine, which have been conjugated with colloidal gold, are impregnated on a porous pad overlapping the bottom end of the membrane. To perform the Amphetamine Urine Cassette test, urine is dispensed into the sample well of the cassette. By capillary attraction, the urine sample will flow towards the other end of the test strip. The antibody-gold conjugate dissolved by the urine sample will flow with the liquid front. In the absence of amphetamine, the antibody-gold conjugate will bind to the immobilized drug conjugate of the test zone causing a visible red band to appear on the test zone. In the presence of amphetamine in the urine sample, antibody-gold conjugate will bind with the free drug in the urine. Sufficient amount of amphetamine will saturate the binding capacity of the antibodies and no visible band will appear on the test zone.

## Sample Collection

Plastic or glass containers can be used for collecting urine samples. Refrigerate samples after collection, until ready to test. Sample should be tested immediately or within three days of collection. Freeze samples that must be stored long-term. Highly turbid urine should be centrifuged prior to testing.

## Warnings and Precautions

1. The Amphetamine Urine Cassette test is for in vitro diagnostics use only.
2. All specimens are considered health hazardous. Use proper protection when handling.
3. The test devices are for one time use only. No test results using used dipsticks are valid.

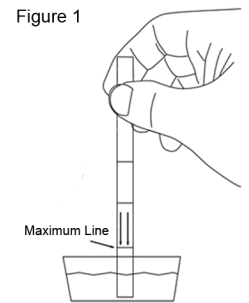
## Storage and Stability

Store the test device at below 28°C. Do not freeze. Prior to use bring test and components to room temperature.

## Test Procedure

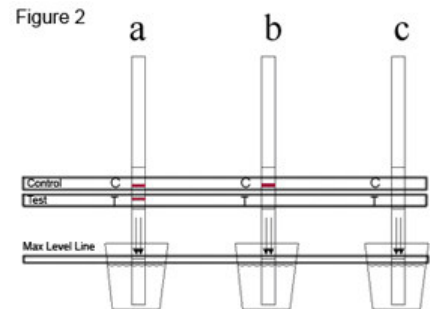
1. Bring test components including urine to room temperature.
2. Remove test strip from the pouch.
3. Dip the test strip with the arrows pointing down into a

container of the urine sample, ensuring that the level of the urine sample does not surpass the maximum level line (Figure 1). Keep contact between the test strip and the urine specimen for 10 seconds or longer. The test strip can then left in the specimen container if the urine level is below the maximum line or remove the test strip from the container and lay it on a flat surface.



4. Read results at 5-10 minutes; do not interpret results after 10 minutes. (see Figure 2).

## Interpretation of Results



**a. Negative:** If there is no detectable amount of Amphetamine present in urine, there will be a rose-color bands appearing on both the control and test section.

**b. Positive:** A positive test result is indicated by the presence of a colored control line (C) and the absence of a test line (T) and indicates a minimum Amphetamine concentration of 1000 ng/ml.

**c. Invalid:** An invalid test result is indicated by the absence of both a test line (T) and a control line (C). If an invalid test result is obtained, it is recommended that the specimen be retested.

\*A positive result indicated here should be confirmed by a non-immunological method, such as GC/MS.

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