

For in-vitro diagnostic and self testing use.
Store at (2-30°C)

INTENDED USE

BIOTEST Methamphetamine Test Strip is a lateral flow chromatographic immunoassay for the detection of Methamphetamine in human urine.

INTRODUCTION

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and addiction. Methamphetamine is referred to by many names, such as Speed, Meth, Chalk, P, Pure and Burn. Methamphetamine hydrochloride comes in the form of clear chunky crystals resembling ice, which can be inhaled by smoking, is referred to as Ice, Crystal, Glass, and Tina.

The drug can be taken orally, injected, or inhaled. 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 Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behaviour, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours, and the drug has a half-life of 9-24 hours in the body.

Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

PRINCIPLE

BIOTEST Methamphetamine 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 Methamphetamine in urine. BIOTEST Methamphetamine Test Strip (Urine) yields a positive result when the Methamphetamine in urine exceeds 1,000ng/mL.

PRECAUTIONS & WARNINGS

1. Do not use the test after the expiration date.
2. If the package is not completely sealed, do not use the test.
3. The test should be performed in a well-lit area.
4. Use the test strip immediately after opening it.
5. The pouch contains a Silica Gel pack to absorb humidity. This pack should not be opened but disposed of safely.
6. At the end of the test, wrap everything you have used in a plastic bag and dispose of it safely. Do not forget to wash your hands properly.

CONTENTS

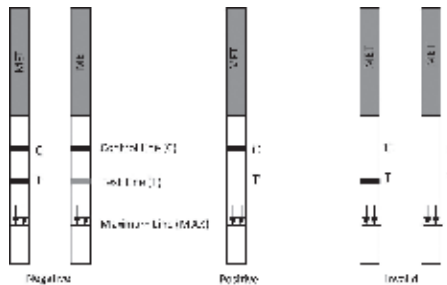
- Test Strip
- Desiccant
- Package Insert

HOW TO USE THE TEST

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 it.
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 illustrations 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 Methamphetamine concentration is below the detectable level (1,000ng/mL). The shade of red in the test line region (T) may vary, but it should be considered 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 Methamphetamine concentration exceeds the detectable level (1,000ng/mL).

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.

LIMITATION OF THE TEST

1. The BioTest Urine Test Strip provides only a preliminary analytical result.
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 a drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.

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