

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

INTENDED USE

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

INTRODUCTION

Marijuana (THC Δ^9 -tetrahydrocannabinol) is a green or gray mixture of dried, shredded flowers and leaves of the hemp plant *Cannabis sativa*. There are over 200 terms for Marijuana including Pot, Herb, Weed, Boom, Mary Jane, Gangster, Chronic, Dak, Grass, Hash and Skunk. It is usually smoked as a cigarette (called a joint) or in a pipe or bong. Some users also mix Marijuana into foods or use it to brew tea.

If someone is high on Marijuana, they might seem dizzy and have trouble walking, act silly and giggly for no reason, have very red bloodshot eyes, have a hard time remembering things that have just happened and when the early effects fade, a few hours later, the user can become very sleepy.

Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-A-tetrahydrocannabinol-9-carboxylic acid (A9-THC-000H).

PRINCIPLE

BIOTEST Marijuana 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 Marijuana in urine. BIOTEST Marijuana Test Strip (Urine) yields a positive result when the Marijuana in urine exceeds 50ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

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

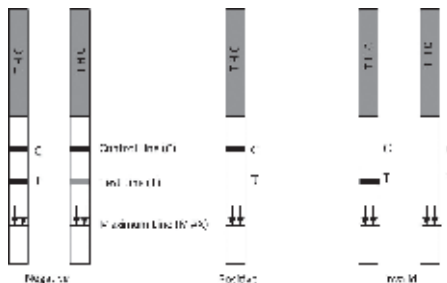
- Test Strip
- Desiccant
- Package Insert

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 Marijuana concentration is below the detectable level of 50ng/mL. The shade of red in the test 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 Marijuana concentration is above the detectable level of 50ng/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.

IFU-BT-THC-S.V.1.2015