

ONE STEP DAGGA TEST STRIP (URINE)

PRINCIPLE

The One-Step THC Test is a one-step immunoassay in which a chemically labelled drug (drug conjugate) competes with the drug which may be present in urine for limited antibody binding sites. The test strip contains a membrane which was pre-coated with drug conjugate on the test band.

A coloured anti- THC monoclonal antibody-colloidal gold conjugate pad is placed at the right end of the membrane. In the absence of drug in the urine, the solution of coloured antibody-colloidal gold conjugate and urine moves upward, chromatographically by capillary action, across the membrane.

This solution then migrates to the immobilized drug conjugate zone on the test band region. The coloured antibody-colloidal gold conjugate then attaches to the drug conjugate to form a visible line as the antibody complexes with the drug conjugate. Therefore, the formation of a visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug / metabolite antigen competes with the drug conjugate on the test band region for limited antibody sites on the anti- THC monoclonal antibody-colloidal gold conjugate. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the coloured antibody-colloidal gold conjugate to the drug-conjugate zone on the test band region. Therefore, absence of the colour band on the test region indicates a positive result.

A control band with a different antigen / antibody reaction is also added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear, regardless of the presence of drug or metabolite. This means that negative urine will produce two coloured bands, and positive urine will produce only one band. The presence of this coloured band in the control region also serves as (1) verification that sufficient volume has been added, and (2) that proper flow was obtained.

STORAGE AND STABILITY

- The test kit should be stored refrigerated or at a temperature 4~30°C (39~86°F).
- Each test should remain in its sealed pouch for the duration of the shelf-life.

PRECAUTIONS

- For in-Vitro diagnostic use
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample
- Do not use after expiration date

SPECIMEN COLLECTION AND HANDLING

The One-Step THC Test is formulated for use with urine specimens.

The test should be performed as soon as possible after a urine specimen has been collected, preferably during the same day.

The specimen may be refrigerated at 2~8°C for 2 days, or frozen at -20°C for a longer period of time.

Specimens that have been refrigerated must be equilibrated at room temperature prior to testing.

Specimens previously frozen must be thawed, equilibrated to room temperature and mixed thoroughly prior to testing.

NOTE: Urine specimens and all materials coming in contact with them should be handled and disposed of as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

TEST PROCEDURE

Review *specimen collection* instructions.

Test strips, patient's samples and controls should be brought to room temperature (10~30°C) prior to testing.

Do not open pouches until ready to perform the assay.

Remove test strip from pouch (bring the test to room temperature before opening the pouch so as to avoid condensation of moisture on the membrane)

Immerse the test strip into the urine sample with the arrow end pointing towards the urine. Do not immerse the test strip above the printed MAX line mark. After a minimum of 15 seconds, remove the test strip from the urine and lay flat on a non-absorbent clean surface.

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Read the results after 5 minutes.
Do not read or interpret the results after 8 minutes.

INTERPRETATION OF RESULTS

Negative (-)

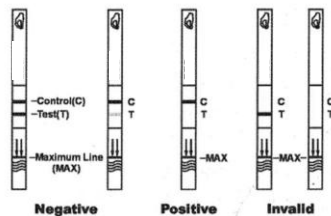
Two rose-pink lines (bands) are visible in the control (C) and the test (T) regions. The intensity of the test line may be less than that of the control line, this still means a negative result.

Positive (+)

A rose-pink band is visible in the control (C) region. No color band appears in the test (T) region.

Invalid

The test is invalid if the control line is not visible at five minutes.
The test failed, or the test procedure was not followed properly.
Verify the test procedure and repeat the test with a new test strip.



Disclaimer: The manufacturer, importer, distributor, pharmacy and medical professional does not accept any liability whatsoever for any consequent actions resulting from interpretations of the test result.

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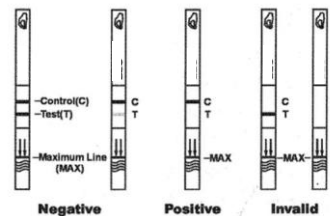
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