MULTI-DRUG TEST

Easy to use rapid Self-Test for the detection of
5 Drugs: Amphetamine, Methamphetamine,
Cocaine, Opiates and Marijuana in urine

INSTRUCTIONS FOR USE

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Prevention at home.

Introduction

The MULTI-DRUG TEST is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which are used for the analysis of specific compounds in biological fluids.

Urine-based screening tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most accepted method for screening urine for drugs of abuse.

The MULTI-DRUG TEST

Registered to device.

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**CONTENT**
- 1 panel card for 5 drugs (AMP, M-AMP, MOR, THC)
- 1 desiccant bag
- 1 instructions leaflet

**STORAGE AND STABILITY**
1) The MULTI-DRUG TEST should be stored at any temperature between 4-30°C. Do not freeze the test kit.
2) The MULTI-DRUG TEST is stable until the expiry date stated on the package label.

**PRECAUTIONS**
1) This test is exclusively intended to in vitro diagnostic self-testing use.
2) The assay is designed for use with human urine only. Fresh urine specimens should be used, and the urine does not require any special handling or pretreatment.
3) Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected.
4) Keep out of the reach of children.
5) Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
6) Store between +4°C and +30°C. Do not freeze.
7) Do not re-use the test device.
8) After use, all the components could be discarded in a dustbin.

**LIMITATIONS**
1) A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
2) There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results, such as technical or procedural errors.
3) This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA).
4) Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

**ASSAY PROCEDURE**
1) Allow samples and panel card to come to room temperature prior to testing.
2) Remove the card from its protective wrapper by tearing along the split.
3) Label card with the patient’s name or control number.
4) Fill the urine container with specimens.
5) Dip vertically the Drugs panel card into urine and hold it for 5-10 seconds. Do not dip over the blue area.
6) Read the results after 3-5 minutes. Do not read the result after 8 minutes.

**READING TEST RESULTS**
**ATTENTION:** The interpretation of the results must be done for each Drug parameter separately.

**POSITIVE**
Only 1 coloured band is visible in result windows.

**NEGATIVE**
2 coloured bands are visible in result windows.

**INCONCLUSIVE**
If there is no distinct colour band, it is recommended to repeat the test with another card.

**NOTE:** A very faint line on the test region indicates that the Drugs in the sample is near or below the cut-off level for the test. However, if any clearly distinguishable line is observed on each window, the sample is NEGATIVE.

**PERFORMANCE CHARACTERISTICS - SENSITIVITY**
- The DRUG-TEST for Amphetamine is used for the detection of amphetamine at a cut-off concentration of 300 ng/ml.
- The DRUG-TEST for Methamphetamine is used for the detection of Methamphetamine at a cut-off concentration of 500 ng/ml.
- The DRUG-TEST for THCA is used for the detection of THC at a cut-off concentration of 50 ng/ml.

**SYMBOLGY**
- U - urine
- 5-10 sec. - Read the results after 3-5 minutes
- Do not use
- Product Code
- Product Lot
- Made in Germany

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A colored anti-drug polyclonal or monoclonal antibody colloid gold conjugate pad is placed at the left end of the membrane. In the absence of drug in the urine, the colored antibody-collod gold conjugate moves along with the sample solution upward the membrane chromatographically by the capillary action across the membrane to the immobilized drug conjugate zone on the test region and is attached to the drug conjugate forming a visible line as the antibody complexes with the drug conjugate. Therefore, the formation of a visible precipitant on the test zone occurs when the test urine is NEGATIVE for the drug. When drug is present in the urine, the drug/metabolite antigen competes with drug conjugate on the test region for the limited antibody sites on the anti-Drug polyclonal or monoclonal antibody-collod gold conjugate. When an adequate amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-collod gold conjugate to the drug conjugate zone on the test region. Therefore, absence of the color band on the test region indicates a POSITIVE result. A control region is also added to the immunochromatographic membrane strips to indicate that the test is performed properly. This control line should always be seen regardless the presence of drug or metabolite. This means that a NEGATIVE urine will produce two colored bands, and a POSITIVE urine will afford only one band.

**SPECIMEN COLLECTION AND PREPARATION**
- The MULTI-DRUG TEST is formulated for use with urine specimens.
- Urine samples should be collected such that testing may be performed as soon as possible after the specimen collection, preferably during the same day as specimen collection.
- The specimen may be refrigerated at 2-8°C for 2 days or frozen at -20°C for longer periods.
- Specimens that were refrigerated must reach room temperature (15-25°C) prior to testing.
- Specimens previously frozen must be thawed and mixed thoroughly prior to testing. Avoid repeated freezing and thawing cycles.

**NOTE:** Urine specimens and all materials coming in contact with them should be handled and disposed as if it is infectious and capable of transmitting infection. Avoid contact with skin.

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