

BIOCARD™ MOR Test

Biocard™ MOR Test is a rapid, simple and reliable immunochromatographic test for the qualitative detection of morphine and their metabolites in human urine.

Carefully read the instructions for use before testing. To perform a Biocard™ MOR Test you will also need a timer and specimen collection container. Perform the test in a well illuminated place.

PRINCIPLE OF THE TEST

The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide both might be found in the urine of the person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of the morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine and/or codeine use.

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 widely accepted method for screening urine for drugs of abuse. The Biocard MOR Test is based on principle of the highly specific immunochemical reactions of antigens and antibodies that are used for the analysis of specific compounds in biological fluids. This test is a rapid, visual competitive immunoassay that can be used for the qualitative detection of morphine in human urine.

Biocard MOR Test in a one-step immunoassay in which a chemically labeled drug (drug conjugate) competes with a drug that may present in urine for limited antibody binding sites. The test stick contains a membrane zone that was pre-coated with drug conjugate on the test band. A colored anti-morphine monoclonal antibody-colloidal gold conjugate pad is placed at the right end of the membrane. In the absence of the drug in the urine, the solution of the colored 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 in the test band region, the colored antibody-colloidal gold conjugate is then attached to the drug conjugate to form a visible line as the antibody complexes with a 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-morphine 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 colored antibody-colloidal gold conjugate to the drug conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a **positive** result; only control lines appear. 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 been performed properly. This control line should always appear, regardless of the presence of drug and metabolite. This means that a **negative** urine will produce two colored bands and **positive** urine will produce only one band. The presence of this colored band in the control region also served as 1) verification that sufficient volumes has been added, and 2) that proper flow was obtained.

CONTENTS:

4-001-050:

50 Test sticks in aluminum tube
1 package leaflet with instructions for use.

PRECAUTIONS:

- ❖ The Biocard MOR Test is designed for *in vitro* use with human urine only according to the instructions for use.
- ❖ If the instructions for use are not followed in detail, outcome of the test may be false.
- ❖ Do not reuse tests.
- ❖ General laboratory procedures and precautions shall be followed in the handling and disposal of samples and used materials.
- ❖ Do not use the test after the expiry date.
- ❖ Do not use the test if the aluminum tube is damaged or left unsealed

- ❖ After the stick has been removed from aluminum tube, the test should be carried out within the next 10 minutes.
- ❖ Avoid cross-contamination of urine samples by using new specimen container and pipette for each urine samples
- ❖ The test is sensitive to humidity as well as to heat. Perform the immediately after removing the test stick from the tube.

STORAGE AND STABILITY

The test kit should be stored refrigerated or at room temperature + 2 ... +30 °C (36-86 °F) in the sealed tube for the duration of the shelf-life.

SAMPLES

Biocard MOR Test is intended for use with human urine samples. Fresh urine does not require any special handling or pretreatment. Urine samples should be collected such that testing can be performed as soon as possible after the specimen collection, preferably during the same day. The specimen may 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 to room temperature, and mixed prior to the tests.

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 practice.

TEST PROCEDURE

Test sticks and samples should be brought to room temperature before testing. Do not open test tube until just before use. When the test stick has been removed from the protective aluminum tube you should carry out the test within 10 minutes. Seal carefully the tube after removing the needed amount of test sticks in order to protect remaining sticks inside in the tube.

A. In case of using pipette

- 1) Add 100 ≈ 120 µl of urine into test tube
- 2) Place the Biocard MOR stick in the tube.
- 3) Read the result 5-8 minutes after the addition of sample.



B. In case of using Biocard MOR Stick with sample container

- 1) Collect the urine specimen in a clean sample container
- 2) Ensure that only sufficient quantity of the specimen is collected to allow submerging the sample pad area of the dipstick (about 1 cm).
- 3) Immerse the Biocard MOR Stick up to marked with "MAX" into the urine sample container. If urine sample touches above the "MAX" which is the reaction zone, the dipstick is defective.



- 4) Observe for the release of colloidal gold complex on the membrane, This would be seen as a pink moving front on the membrane and could take 5 to 10 seconds to appear depend on sample.
- 5) Remove the test stick and place horizontally on a flat surface.

Read the result 5-8 minutes after the addition of the samples.

INTERPRETATION OF THE RESULTS

Negative result: Two line appears (C,T)



The presence of two color bands ("T" and "C") band within the result window, No matter which band appears first, indicates a negative result. **Negative result** indicates that the drug concentration is below detectable level (< 300 ng/ml).

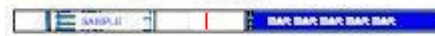
Positive: One line appear (C)

The presence of one purple color band ("C") within result window indicates morphine **positive** result. This positive result indicates that the concentration of morphine and it's metabolites is at or above the detection level.



In case of low-density bands:

The cooler test bands ("T") within result window, faint or weak, indicates the presence of a few quantity of drug substance that may ingested by several cases but close to the cut-off value; Therefore, the result should be re-tested or confirmed with a more specific methods before a positive determination is made.



If control line is not formed, you have likely not followed the instruction for use or test unit is damaged. In such a case repeat the testing with new test unit.

CUT-OFF

Sensitivity of Biocard™ MOR Test is adjusted so that 300 ng/ml of morphine and it's metabolites in human urine gives a positive test result. The cut-off values in drug screening devices are adjusted to the demands of the American National Institution on Drug Abuse (NIDA).

WARNINGS AND LIMITATIONS

- ❖ The Biocard MOR Test provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) are the preferred confirmatory methods.
- ❖ Biocard MOR Test is qualitative screening assay and cannot determine either the drug concentration in the urine or the level of intoxication.
- ❖ 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.
- ❖ In case of undeterminable test result, repeat the testing by using a new device. If repeated test results were the same, another technically available tests should be performed and a definite clinical diagnosis should not be based

on the results of a single test. Clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated and should be conjunction with the clinical symptoms and all laboratory data.

REFERENCES

1. Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man, Biomedical Publications, Davis, CA, 1982
2. Urine testing for drugs of Abuse. National Institute on Drug Abuse (NIDA) Research Monograph 73, 1986
3. Fed.Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11979, 1988
4. McBay A.J Clinical Chem 33, 33B-40B, 1987
5. Gilman, A.G and Goodman L.S The pharmacological Basis of Therapeutics., eds Mac Millan Publishing, New York NY 1980

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