

Morphine 300 Rapid Test Device

A competitive immunochromatographic immunoassay for the visual detection of morphine in urine

Catalog #:DA1002C

INTRODUCTION

The opiates such as heroin, morphine, and codeine are derived from the resin of the opium poppy. Morphine and morphine glucuronide might both be found in the urine sample of a person who has taken morphine. Heroin and Codeine are quickly metabolized to morphine in the body. Therefore, the presence of morphine or the metabolite, morphine glucuronide, in urine, is an indication of heroin, morphine and/or codeine use.

The MOP-Card for morphine is a lateral flow, one-step, competitive immunoassay. This one step test is fast and easy, and results are read visually without the need for instrumentation. The test system employs unique monoclonal antibodies to selectively identify morphine in urine samples with a high degree of sensitivity. The cut off concentration for morphine has been developed at 300 ng/ml, the concentration set by the National Institute on Drug Abuse for the qualitative detection of morphine in human urine. This product is not intended to monitor drug levels, but only to screen urine for the presence of morphine.

Note: This test provides only a preliminary analytical test result which should be confirmed by a more specific method. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND PRINCIPLE OF THE TEST

The MOP-Card for Morphine is based on the principle of a competitive inhibition immunoassay, in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine, for limited antibody binding sites. The test device consists of a membrane strip, which is pre-coated with morphine-BSA conjugate on the test band region, and a colored anti-morphine monoclonal antibody-colloid gold conjugate pad, which is placed at the end of the membrane. In the absence of drug in the urine, the colored antibody-colloid gold conjugate moves with the sample by capillary action along the membrane until it reaches the immobilized drug conjugate in the test band region. At this point, the antibody-colloid gold conjugate reacts with the pre-coated drug conjugate and forms a visible red colored line as the antibodies form complexes with the drug conjugate. Therefore, the formation of a **visible color line** on the test band region, shows the urine sample tested for morphine is **negative**. When the drug is present in the urine, the drug/metabolite antigen will compete with the drug conjugate coated in the test band region for the limited antibody sites. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites, and thus will prevent attachment of the colored antibody-colloid gold conjugate to drug conjugates pre-coated in the test band region. Therefore, absence of the color band on the test region indicates a **positive result**. A control band with a different antigen/antibody reaction is also added to membrane strip to indicate that the test is performed properly. This control line should always be seen. A negative urine sample produces two distinct color bands, and a positive sample produces only one color band in the control zone.

REAGENTS AND MATERIALS

MOP-Card: 50tests/box

PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Do not use the test device beyond the expiration date.
3. Use a new specimen container and dropper for each test to avoid cross contamination of urine samples.
4. Urine specimens may be infectious, properly handle and dispose of all used reaction devices in a biohazard container.

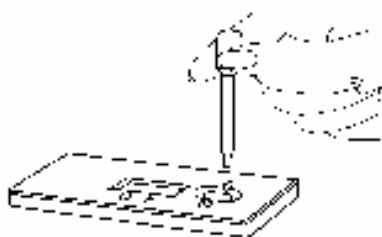
SPECIMEN COLLECTION AND PREPARATION

A fresh urine specimen should be used, no special pre-treatment is necessary. The specimen may be refrigerated (2-8°C) and stored up to 2 days, or frozen (-20°C or below) prior to assaying. If samples are refrigerated they should be brought to room temperature before testing.

STORAGE OF TEST KIT

The MOP-Card can be stored at any temperature between 4-30°C.

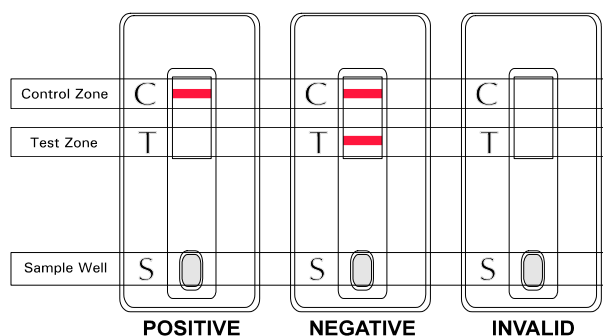
ASSAY PROCEDURES



1. Bring the test components and urine sample to room temperature before testing. Do not open foil pouch until ready to begin testing.
2. Open the foil pouch and remove the test device.
3. Place the device on a clean, level surface.
4. Holding the dropper vertically, dispense 4 drops (~ 120ul) of urine without air bubbles into the sample well "S" of the test device.
5. Read results at 5 minutes.

IMPORTANT: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



1. **Positive.** In addition to one pink colored control (C) line in the control region, a distinct pink colored line will also appear in the patient test (T) region. The color intensity of the test line may be weaker or stronger than that of the control line.
2. **Negative.** Only one colored line appears in the control (C) region. No apparent line in the patient test (T) region. This indicates the presence of a drug/metabolite at a level of 300ng/ml or above.
3. **Invalid.** No line appears in the control zone "C". An invalid result may be due to improper testing procedures or deterioration of the kit components. Repeat the assay sequence using a new device.

Note: There is no meaning attributed to line color intensity or width.

LIMITATION

1. This product is designed for use with human urine only.
2. Although the test is very accurate, there is a possibility that false results will occur due to the presence of interfering substances in the urine.
3. The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of morphine.
4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen and retest.

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