

**CORTEZ DIAGNOSTICS, INC.**

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See external label



2°C-30°C



Σ=25 or 50 tests



Cat. #121059-1

OneStep Morphine RapiDip InstaTest**Cat. No. 121059-1****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. The presence of morphine or the metabolite, morphine glucuronide, in urine, is an indication of heroin, morphine and/or codeine use.

Cortez Diagnostics, Inc. One Step Test for morphine is a lateral flow, one-step, competitive immunoassay. This one step test is fast and easy; the results are read visually without the use of an instrument. 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 is 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 samples 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.

PRINCIPLE OF THE TEST

Cortez Diagnostics, Inc. One Step Test 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 the limited number of 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 to produce a visible red colored line as the antibodies form complexes with the drug conjugate. The formation of a **visible color line** on the test band region indicates 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.

SPECIMEN COLLECTION

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.

TEST PROCEDURE

2. Immerse the strip into the urine sample with the arrow end pointing towards the urine. Do not immerse past the Mark line. Take the strip out after 3 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g., mouth of the urine container).
3. Wait for colored bands to appear. Read results in 10 minutes. Results obtained after more than 15 minutes are not considered valid.

INTERPRETATION OF RESULTS

- **Negative:** 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.
- **Positive:** 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 300 ng/mL or above.
- **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:** A faint line on the test region means that the morphine in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond the expiry date.
3. The test device should not be reused.
4. Urine specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.

1. Bring the test pouch to room temperature. To begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.



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