

Opiate Urine Dipstick Test OPI-DS04300

Name and Intended Use

The Opiate Urine Dipstick Test qualitatively detects morphine and morphine metabolites in human urine. The results obtained are of a preliminary nature; positive results should be confirmed by way of a non-immunological method, such as gas chromatography mass spectrometry (GC/MS).

Summary of Test

Morphine is an opiate compound, as well as a metabolite of heroin. These compounds function as analgesics by depressing the central nervous system. Most of heroin injected is metabolized to morphine and codeine; morphine can be detected in a user's urine several days after ingestion.

Principle of Procedure

The Opiate Urine Dipstick Test is an immunochromatography device based on the principle of competitive immunoassay. The nitrocellulose membrane of the dipstick is immobilized with morphine-BSA conjugate at the test zone (see Figure 1). Antibodies against morphine, which have been conjugated with colloidal gold, are impregnated on a sample filter pad overlapping the bottom of the membrane. When the sample pad of the dipstick is dipped into the urine sample to perform the test, the urine will migrate upwards through the pad. The antibody-gold conjugate will flow with the liquid front and, in the absence of morphine, will bind to the immobilized drug conjugate resulting a visible red band to appear at the test zone. However, when a sufficient concentration of morphine is present in the urine sample, antibody-gold conjugate will bind with the free drug; thus, due to competitive binding, no visible band will appear at the test zone.

Sample Collection

Urine samples should be collected in either plastic or glass containers. Refrigerate samples after collection, until ready to test. Sample should be tested within three days of collection. Freeze samples that must be stored long-term. Highly turbid urine should be centrifuged prior to testing.

Warnings and Precautions

1. The Opiate Dipstick is for in vitro diagnostics use only.
2. All specimens are considered health hazardous. Use proper protection when handling.

Storage and Stability

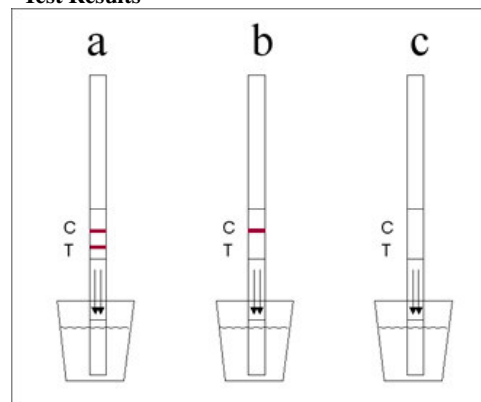
- Store the test below at 4 °C - 30°C. Do not freeze the test device.
- Bring refrigerated test and components to room temperature before testing.

Assay Procedure

1. Bring test components including urine to room temperature.
2. Remove test strip from the pouch.
3. Dip the test strip with the arrows pointing down into a container of the urine sample, ensuring that the level of the urine sample does not surpass the edge of the arrow tape. Keep contact between the test strip and the urine specimen for 5 seconds or longer.
4. Read results at 5-10 minutes; do not interpret results after 10

minutes. (see Figure1).

Figure 1 – Test Results



Interpretation of Results

- NEGATIVE:** If there is no morphine present in urine, there will be a rose-color bands appearing on both the control and the test section.
- POSITIVE:** A positive result is observed when there is a control line and no test line and indicates a **minimum** morphine concentration of 300 ng/ml. At concentrations less than 300 ng/ml, there may be weak signal appearing at the test line area.
- INVALID:** If there is no rose-color band visible in the control window, then the test result is invalid. It is recommended that the urine be retested.

*A positive result indicated here should be confirmed by a non-immunological method, such as GC/MS.

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