One Step Morphine (300) Test (Cassette)

CAT: DT50110 – 25

INTENDED USE
The One Step Morphine Test is a rapid qualitative, competitive binding immunoassay intended to provide qualitative screening results for morphine in human urine at a cutoff level of 300 ng/ml.

The US Substance Abuse and Mental Health Services Administration (SAMHSA) recommends the screening level for morphine to be at a concentration of 2000 ng/ml.

Always justify preliminary positive and negative results with compelling clinical evidence and professional judgment. The test provides only preliminary data which should be confirmed by other methods such as GC/MS.

SUMMARY AND EXPLANATION OF THE TEST
The One Step Morphine Test is an easy, fast, and visually read screening method without the need for instrumentation. The test system employs unique polyclonal antibodies to selectively identify morphine in urine samples with a high degree of sensitivity.

Morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine) belong to class of drugs called opiates. Opiates are central nervous system stimulating drugs. It’s overdose and extended use may lead to substance abuse, which may cause severe and/or permanent damage to the human nervous system. Morphine is rapidly absorbed from an oral dose and from intramuscular and subcutaneous injection. It is metabolized extensively, with only 2-12% excreted as unchanged morphine in the urine. The quantitatively most important metabolite is excreted to the extent of 67-70% of the given dose in urine in 48 hours. Heroin is rapidly metabolized to morphine in the body and excretion pattern of heroin is similar to morphine. Codeine is extensively metabolized, 10-15% of the dose is dimethylated to form morphine and norcodeine.

PRINCIPLE
The One Step Morphine Test is a lateral flow chromatographic immunoassay. Morphine in the urine specimen competes with the morphine-BTG (Bovine Thyroglobulin antigen coated at the T line) on the nitrocellulose membrane for the limited binding sites of the anti-morphine antibodies in the conjugate pad.

When a proper amount of urine specimen is applied to the sample well, the urine migrates by capillary action through the test strip. If the morphine level in the urine sample is below the cutoff level of 300 ng/ml, the pink-rose colored antibody gold conjugate will bind to the morphine-BTG antigens coated on the T line. As a result the T line becomes a visible pink-rose line.

If morphine is present in the urine sample at a cutoff level of 300ng/ml, or higher, it will bind with the anti-morphine antibody conjugate so that no pink-rose line develops in the T region, indicating a positive result.

The C line is coated with goat anti-mouse antibody that will bind to the gold-antibody conjugate and form a pink-rose colored line regardless of the presence of morphine.

A negative specimen produces two distinct color bands, one in the test zone and one in the control zone. A positive specimen produces only one color band in the control zone.

REAGENTS AND MATERIALS SUPPLIED
1. Test Cassette each sealed in a pouch with a dropper pipette and a desiccant.
2. Test Instructions.

MATERIALS REQUIRED, BUT NOT PROVIDED
1. Clock or timer
2. Sample collection containers

WARNINGS AND PRECAUTIONS
1. For in vitro diagnostic use only.
2. Do not use kit beyond the expiration date.
3. Urine specimens may be infectious: properly handle and dispose of all used reaction devices in a biohazard container.

STORAGE AND STABILITY
Store the kit at room temperature (15-30°C); do not freeze. The unopened device can be used until the expiration date marked on the pouch.

SAMPLE COLLECTION AND PREPARATION
Collect urine sample in a clean, dry container, without any preservatives. Urine specimens may be refrigerated (2-8°C) and stored up to 48-72 hours. For longer storage, samples should be frozen (-20°C or below). Frozen or refrigerated samples must be brought to room temperature before testing.

Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE
1. Bring the test components to room temperature before opening the pouch.

2. Remove the Test Device from the foil wrapper by tearing along the “notch” and place it on a flat surface.
3. Fill the Transfer Pipette with urine sample.
4. Holding the dropper vertically, dispense exactly four full drops of urine (without air bubbles) into the sample well (S).
Note: If the migration is not observed in 30 seconds in the results window, add one or two extra drops of urine specimen.
5. Read the test result between 4 to 7 minutes after adding the specimen.

IMPORTANT: In order to prevent incorrect readings, do not interpret test results after seven (7) minutes.

INTERPRETATION OF RESULTS

Positive: A pink-rose color band appears in the control zone “C” but not in the test zone “T”. This is a positive result and indicates the morphine level is at or above the detection sensitivity of 300 ng/mL. Positive results should be confirmed with a more specific method before a positive determination is made.

Negative: Two horizontal rose-pink color band appear. one in the control zone “C” and one in the test zone “T”. This is a negative result and indicates the morphine level is below the detection sensitivity of 300 ng/mL. A very faint line in the test region should be considered negative.

Invalid: If there is a visible band in the test zone but not in the control zone or if there are no distinct color bands visible in both the test zone and the control zone then the test is invalid. In this instance, retesting of the specimen is recommended.

QUALITY CONTROL
1. An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.
2. The use of an external control procedures is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.
LIMITATIONS OF THE PROCEDURE
1. This product is designed to be used for the detection of morphine in human urine only.
2. Although the test is very accurate in detecting the morphine level in urine, interfering substances in the test sample can cause false result.
3. The test is a qualitative screening assay and is not suggested for determining quantitative morphine levels in urine or the level of intoxication.
4. Adulterants, such as bleach or other strong oxidizing agents, if present in urine specimens, can produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.
5. Urine sample with bacterial contamination should be used. The samples may interfere with the test and give false results.

PERFORMANCE CHARACTERISTICS
1. SENSITIVITY (CUT-OFF)
   This test can detect morphine in urine at a cutoff level of 300ng/ml or higher.
2. ACCURACY
   A study was performed at a Reference Laboratory and three different Physician Office Laboratory (POL). 94 clinical samples analyzed by GC/MS for morphine from a toxicology laboratory were blind labeled and tested. Each sample was tested at each site and compared with GC/MS results of morphine only. (Codeine was not considered during the analysis.) The test demonstrated an overall agreement of greater than 96.5%.

3. PRECISION
   The precision was determined at three different POL locations, by persons with diverse educational backgrounds and work experience. Forty-pooled drug-n urine specimens were spiked with morphine at different levels. All specimens were blind labeled and tested. The results are as follows:

<table>
<thead>
<tr>
<th>Biological Analytes</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin (serum)</td>
<td>2000 µg/ml</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>1000 µg/ml</td>
</tr>
<tr>
<td>Creatine</td>
<td>1000 µg/ml</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1000 µg/ml</td>
</tr>
</tbody>
</table>

INTERFERING SUBSTANCES
The following compounds, usually found in urine, were spiked in urine pools containing 0 or 300 ng/ml morphine were tested accordingly in the D9Tek’s Morphine Urine Test. No effects were observed from those Analytes at 1.0 mg/ml.

SPECIFICITY
Cross-Reactivity
A study was conducted using morphine-related compounds to determine the cross reactivity of the test.

Morphine structurally related compounds showing the lowest concentrations of the drug producing a positive response equivalent to the cutoff level:

<table>
<thead>
<tr>
<th>Description</th>
<th>Conc. (ng/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>300</td>
</tr>
<tr>
<td>Codeine</td>
<td>300</td>
</tr>
<tr>
<td>Ethyl Morphine</td>
<td>300</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>400</td>
</tr>
<tr>
<td>Morphine-glucuronide</td>
<td>500</td>
</tr>
<tr>
<td>Merperidine</td>
<td>30000</td>
</tr>
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The results indicate a 92.5% concordance with the expected results.

BIBLIOGRAPHY

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