The MOP One Step Morphine Test Device is a lateral flow chromatographic immunoassay for the detection of morphine s in urine at a cut-off concentration of 300ng/mL. This test will detect other morphine, please refer to analytical specificity table in this package insert. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

### SUMMARY

Morphine is a pain medication of the morphine type. It acts directly on the central nervous system (CNS) to decrease the feeling of pain. It can be used for both acute pain and chronic pain. It can be given by mouth, by injection into a muscle, by injecting under the skin, intravenously, into the space around the spinal cord, or rectally. Maximum effect is around 20 min when given intravenously and 60 min when given by mouth while duration of effect is between three and seven hours.

Potentially serious side effects include a decreased respiratory effect and low blood pressure. Morphine has a high potential for addiction and abuse. Common side effects include drowsiness, vomiting, and constipation.

The MOP One Step Morphine Test Device is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of morphine in urine. The MOP One Step Morphine Test Device yields a positive result when the concentration of morphine in urine exceeds the cutoff level.

### PRINCIPLE

The MOP One Step Morphine Test Device is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Morphine, if present in the urine specimen below the cutoff level, will not saturate the binding sites of the antibody in the test device. The morphine conjugate will be captured by antibody and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the morphine level exceeds the cutoff concentration because it will saturate all the binding sites of anti-morphine antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

The test device contains monoclonal anti-morphine antibody-coupled particles and morphine-protein conjugates. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For professional in vitro diagnostic use only. Do not use after the expiration date. The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded according to national and local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

#### Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

#### Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

#### Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls

### DIRECTIONS FOR USE

Allow the test device, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100μl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

### INTERPRETATION OF RESULTS

(Please refer to illustration above)

#### NEGATIVE: *

One colored line should be in the control region (C), and another colored line should be in the test region (T). This negative result indicates that the morphine concentration is below the detectable level (300ng/mL).

#### NOTE: The shade of the color in the test region (T) may vary, but it should be considered negative whenever there is even a faint line.

#### POSITIVE: One colored line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the morphine concentration exceeds the detectable level (300ng/mL).

#### INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Users should follow national and local guidelines for testing QC materials.

### LIMITATIONS

1. The MOP One Step Morphine Test Device provides only a qualitative, preliminary analytical test result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.  
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. 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.
4. Certain medications containing morphine derivatives may produce a positive result. Additionally, foods and tea containing poppy products (the origin of the morphine) may also produce a positive result.
5. A Positive Result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
6. A Negative Result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of
A side-by-side comparison was conducted using the MOP One Step Morphine Test Device and a leading commercially available MOP rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

<table>
<thead>
<tr>
<th>Method</th>
<th>Other MOP Rapid Test</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>150</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>150</td>
</tr>
<tr>
<td>Total Results</td>
<td>150</td>
<td>150</td>
</tr>
</tbody>
</table>

% Agreement with this commercial kit: -99%, -99%, -99%

When compared to GC/MS at the cut-off of 300ng/mL, the following results were tabulated:

<table>
<thead>
<tr>
<th>Method</th>
<th>GC/MS</th>
<th>Total Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>141</td>
<td>9</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>150</td>
</tr>
<tr>
<td>Total Results</td>
<td>141</td>
<td>159</td>
</tr>
</tbody>
</table>
% Agreement with GC/MS Analysis: >99%, 94%, 97%

Eighty (80) of these samples were also run using the MOP One Step Morphine Test Device by an untrained operator at a different site. Based on GC/MS data, the operator obtained a statistically similar Positive Agreement, Negative Agreement and Overall Agreement rate as the laboratory personnel.

A drug-free urine pool was spiked with Morphine at the following concentrations: 0ng/mL, 150ng/mL, 225ng/mL, 300ng/mL, 375ng/mL and 450ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

<table>
<thead>
<tr>
<th>Morphine Concentration (ng/mL)</th>
<th>Percent of Cutoff</th>
<th>n</th>
<th>Visual Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0%</td>
<td>30</td>
<td>Negative</td>
</tr>
<tr>
<td>150</td>
<td>-50%</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>225</td>
<td>-25%</td>
<td>30</td>
<td>28</td>
</tr>
<tr>
<td>300</td>
<td>Cutoff</td>
<td>30</td>
<td>20</td>
</tr>
<tr>
<td>375</td>
<td>+25%</td>
<td>30</td>
<td>3</td>
</tr>
<tr>
<td>450</td>
<td>+50%</td>
<td>30</td>
<td>0</td>
</tr>
</tbody>
</table>

Specificity:

The following table lists compounds that are positively detected in urine by the MOP One Step Morphine Test Device at 5 minutes.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>300</td>
</tr>
<tr>
<td>Ethylmorphine</td>
<td>6,250</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>50,000</td>
</tr>
<tr>
<td>Levophanol</td>
<td>3,125</td>
</tr>
</tbody>
</table>

Cross-Reactivity:

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or morphine positive urine. The following compounds show no cross-reactivity when tested with the MOP One Step Morphine Test Device at a concentration of 100ng/mL:

- 4-Acetamidophenol
- Amphetamine
- 4-Methylamphetamine
- Betaxolol
- Betaxolol hydrochloride
- Betaxolol mesilate
- Betaxolol succinate
- Betaxolol tartrate
- Betaxolol tosylate
- Betaxolol-3 mesilate

BIBLIOGRAPHY:

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA, 1982; 488