6-MAM Rapid Test Dipstick (Urine)  
**Package Insert**  
A rapid test for the qualitative detection of 6-Monoacetylmorphine in human urine. For professional in vitro diagnostic use only.  

[INTENDED USE]  
6-Monoacetylmorphine (6-MAM) or 6-aceetamidomorphine is one of three active metabolites of heroin (diamorphine), the others being morphine and the much less active 3 monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin, and then is either metabolised into morphine or excreted in the urine. 6-MAM remains in the urine for no more than 24 hours. So a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day. 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in urine virtually guarantees that heroin has recently been consumed.  

The 6-MAM Rapid Test Dipstick is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody conjugated to colloidal gold, which reacts with 6-MAM in urine. The 6-MAM Rapid Test Dipstick yields a positive result when morphine in urine reaches 10ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).  

**PRINCIPLE**  
The 6-MAM Rapid Test Dipstick is an immunosay 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. If 6-MAM, in a urine specimen below 10ng/mL, will not saturate the binding sites of the antibody coated particles in the test device, other antibody coated particles will then be captured by the immobilized 6-MAM conjugate and a colored line will show up in the test line region. The colored line will not form in the test line region if the 6-MAM level is at or above 10ng/mL 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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control position indicating that proper volume of specimen has been added and membrane wicking has occurred.  

**SPECIFICATIONS**  
The test contains mouse monoclonal anti-Morphine antibody-coated particles and Morphine-protein conjugate. A rabbit antibody is employed in the control line system.  

**PRECAUTIONS**  
- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.  
- The test should remain at room temperature (15-30º C) prior to testing.  
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.  
- The used test should be discarded according to local regulations.  

**STORAGE AND STABILITY**  
Store as packaged at room temperature or refrigerated (2-30ºC). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test should remain in the sealed pouch or closed canister until use. DO NOT FREEZE. Do not use beyond the expiration date.  

**SPECIMEN COLLECTION AND PREPARATION**  
**Urinalysis**  
The urine specimen must be collected in a clean container. Urine specimens at any time of the day may be used. Urine specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain clear supernatant. The result is invalid.  

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

**MATERIALS**  
- Test Dipsticks  
- Materials Required But Not Provided  
- timer  

[DIRECTIONS FOR USE]  
- For professional in vitro diagnostic use only.  
- The test, urine sample, and/or controls to reach room temperature (15-30º C) prior to testing.  
- Bring the pouch to room temperature before opening it. Remove the Test Dipstick from the sealed pouch and allow it to sit at room temperature (15-30ºC) for 10 minutes.  
- With arrows pointing toward the urine specimen, immerse the Test Dipstick vertically in the urine specimen for at least 10 seconds. Remove the test strip. Examine the test strip for a colored line(s) after 1 minute.  
- Place the Test Dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. Read results at 5 minutes. Do not interpret the results after minute 10.  

**Analytical Specificity**  
The following table lists compounds that are positively detected in urine by the 6-MAM Rapid Test Dipstick at a concentration of 250ng/mL.  

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/mL)</th>
<th>Current (ng/mL)</th>
<th>Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>10</td>
<td>Morphone</td>
<td>20</td>
</tr>
<tr>
<td>Ethylmorphine</td>
<td>200</td>
<td>Norcodeine</td>
<td>200</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>2,000</td>
<td>Norfentanyl</td>
<td>2,000</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>100</td>
<td>Oxycodone</td>
<td>1,000</td>
</tr>
<tr>
<td>Levorphanol</td>
<td>50</td>
<td>Oxymorphone</td>
<td>50</td>
</tr>
<tr>
<td>6-Monoacetylmorphine</td>
<td>10</td>
<td>Fentanyl</td>
<td>50</td>
</tr>
<tr>
<td>Morphine methhydrate</td>
<td>10</td>
<td>Methadone</td>
<td>50</td>
</tr>
</tbody>
</table>

**Sensitivity**  
- A drug-free urine pool was spiked with 6-MAM at the following concentrations: 0ng/mL, 5ng/mL, 7.5ng/mL, 10ng/mL, 12.5ng/mL, 15ng/mL, and 20ng/mL. The result demonstrates that the 6-MAM concentration is below the detection cutoff level.  
- A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision. An identity panel of results comprised according to GC/MS. The 6-MAM 25ng/mL and above and below the 10ng/mL cut-off was provided to each site. The results are given below.  

<table>
<thead>
<tr>
<th>Concentration (ng/mL)</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>7.5</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>20</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Effect of Urine Specific Gravity**  
Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 5ng/mL and 10ng/mL of Morphine. The 6-MAM Rapid Test Dipstick was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.  

**Limitation of Urinary Drug Testing**  
The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with 6-MAM to 5ng/mL and 5ng/mL. The spiked, pH-adjusted urine was tested with the 6-MAM Rapid Test Dipstick in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.  

**Cross-Reactivity**  
A study was conducted to determine the cross-reactivity of the test with compounds in either the urines or drug pools used in the cross-reactivity studies showed that the 6-MAM Rapid Test Dipstick cross-reacted with 6-MAM at a concentration of 10ng/mL.