One Step Tramadol (TRA) Test Dipcard

Package Insert for testing of any combination of the following drugs: Tramadol

A rapid, one step screening test for the simultaneous, qualitative detection of multiple Tramadol and metabolites in human urine.

For forensic use only.

INTENDED USE & SUMMARY

Urine based test for multiple drugs of abuse range from simple immunometric tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse. The One Step Tramadol (TRA) Test Dipcard is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations in urine:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cut-off level (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRA</td>
<td>1500</td>
</tr>
</tbody>
</table>

This test will detect other related compounds, please refer to the 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 to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. This test is also not intended for body fluid specimens as body fluids may produce erroneous results regardless of the most likely reasons for control line failure. Review the procedure and repeat the test using a new test strip. If the problem persists, discontinue using the lot immediately and contact your manufacturer.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-8°C). The One Step Tramadol (TRA) Test Dipcard should remain in the sealed pouch until use. Do not expose the test device to extreme temperature and humidity. Urine specimens may be stored at 2-8°C for up to 72 hours prior to testing. For prolonged storage, specimens may be frozen and stored below 20°C. Freezer specimens should be thawed and mixed well before testing.

SPECIMEN COLLECTION AND PREPARATION

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 vesicant properties should be avoided. Bladder irrigation is not allowed to urine to obtain a clean supernatant for testing.

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

PERFORMANCE CHARACTERISTICS

One Step Tramadol (TRA) Test Dipcard

A dry-fume urine pool was spiked with drugs to the concentrations at ± 50% cut-off level and ± 15% cut-off. The results are summarized below:

<table>
<thead>
<tr>
<th>Drug Concn. (ng/mL)</th>
<th>TRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>±50% Cut-off</td>
<td>0</td>
</tr>
<tr>
<td>±25% Cut-off</td>
<td>0</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>1500</td>
</tr>
<tr>
<td>±50% Cut-off</td>
<td>30</td>
</tr>
</tbody>
</table>

A positive test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1. Remove the test device from the sealed pouch and place the dip card on a clean, dry surface, specimen side up.
2. Remove the cap from the test device. Label the device with patient or control identifiers.
3. Immerse the absorbent tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic device.
4. Replace the cap over the absorbent tip and by the device firmly on a non-abrasive clean surface.
5. Read results at 5 minutes.

DO NOT INTERPRET RESULT AFTER 5 MINUTES.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another red or pink line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the cut-off level.

*NOTE: The shade of red in the test line region (Drug/T) will vary, but it should be considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line 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 used as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The One Step Tramadol (TRA) Test Dipcard provides only a qualitative, preliminary analytical 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. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.

3. Adults, such as chlorpromazine and nortriptyline, 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. A positive result does not indicate level or intoxication, administration route or concentration in urine.

5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.

6. The test does not distinguish between drugs of abuse and certain medications.

7. A positive result may be obtained from certain foods or food supplements.

MATERIALS

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test panel</td>
<td>Package insert</td>
</tr>
<tr>
<td>Meticulousness</td>
<td>Test solution use</td>
</tr>
</tbody>
</table>