For Use Only

The Premier Biotech OralTOX™ is a rapid visual immunosassay for the qualitative, presumptive detection of drugs of abuse in human oral fluid specimens. The test system consists of one or more membrane strips mounted in a plastic cassette.

This test detects the presence of the following drugs at the concentrations listed below. Specific combinations will vary according to the test in question.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Calibrator (ng/mL)</th>
<th>Cut-off (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbiturate</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Benzodiazepine</td>
<td>200</td>
<td>250</td>
</tr>
<tr>
<td>Buprenorphin</td>
<td>1</td>
<td>1.11</td>
</tr>
<tr>
<td>Codeine</td>
<td>30</td>
<td>50</td>
</tr>
<tr>
<td>Cotinine</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Methadone</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>1</td>
<td>1.11</td>
</tr>
<tr>
<td>Morphine</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Nicotine</td>
<td>1.11</td>
<td>2</td>
</tr>
<tr>
<td>THC (Cannabis)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>THC (Cannabis)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>


**PRINCIPLE**

The Premier Biotech OralTOX™ is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding to sites on their specific antibody.

During a test, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of the antibody. The antibody will then react with the drug-antigen conjugate and a visible color will form in the test lane (1) of the specific drug strip. The presence of drug in the oral fluid specimen will generate a color line in the test lane region. A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition. While a drug-negative oral fluid specimen will generate a color line at the test control region (C), indicating that proper volume of specimen has been added and complete mixing has occurred.

**MATERIALS**

Materials Provided
- Individually packed devices and oral fluid collection swabs
- Procedure/Results Record Book

Package insert

**Manufactured for:**
Premier Biotech
7516 8th St. S.
Cottage Grove, MN 55016

**FEIND FEO 1/2016**

**INTRODUCTION**

The Premier Biotech OralTOX™ for AMF/BAR/RUP/BZO/COC/COT/EDDP/KET/METH/MDMA/PMP/PPT/PPX/TAC and metabolites is a rapid oral fluid screening test that can be performed without the use of an instrument. It detects multitudinous narcotics to selectively detect elevated levels of specific drugs in human oral fluid.
SPECIMEN COLLECTION AND STORAGE

- This device is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the specific collection section of this package insert.
- Perform testing immediately after specimen collection.

- 3 specimens to be shipped, pack them in compliance with all applicable regulations for transportation of biological agents.

PROCEDURE

Bray tests, specimens, and/or controls to room temperature (15°C to 30°C) prior to using or opening. Avoid splashing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

1. Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, tongue) several times, then hold swab in mouth until swab moisture (evident by presence of saliva) reaches the swab tip.

- Do not remove swab from the mouth before placing it into the collection tube, thus swabbing for 5 minutes.

- Place swab into collection tube.

- Store the specimen in a refrigerated environment at 2°C to 8°C until testing.

-标本应放在2°C至8°C的环境中保存，直至检测。

2. Set device on centigrade test with test – 12 below.

- Not for use on specimen collected in the past 2 days.

- Place swab into collection tube.

- Store the specimen in a refrigerated environment at 2°C to 8°C until testing.

-标本应放在2°C至8°C的环境中保存，直至检测。

- Positive: Only one colored band appears in the control (C) lane.

- Negative: Two colored bands appear on the membrane. One band appears in the control lane (C) and another band appears in the test lane (T).

- In some cases, if the concentration of analytes is low, a faint band may be observed. A positive result indicates that the drug concentration exceeds the detectable level.

- A negative result indicates that the drug concentration is below the detectable level.

INTERPRETATION OF RESULTS

(See previous illustration)

- Positive: Only one colored band appears in the control (C) lane. No colored band appears in the test (T) lane. A positive result indicates that the drug concentration exceeds the detectable level.

- Negative: Two colored bands appear on the membrane. One band appears in the control lane (C) and another band appears in the test lane (T).

- In some cases, if the concentration of analytes is low, a faint band may be observed. A positive result indicates that the drug concentration exceeds the detectable level.

- Negative: Two colored bands appear on the membrane. One band appears in the control lane (C) and another band appears in the test lane (T).

- An invalid result may be obtained due to the following reasons:

1. Use of test kit after the expiration date indicated on the package.
2. Use the test if the foil pouch is damaged. Do not reuse test kits.

- This contains products of animal origin. Certified knowledge of the origin and/or source of these products may not completely guarantee the absence of transmissible pathogen agents. It is therefore, recommended that laboratory personnel and other individuals as potentially infected, and handled by observing usual safety precautions (e.g., do not ingest or inhale).

- Read the entire procedure carefully prior to testing.

- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle used gloves as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the testing process. Use a good laboratory practice to confirm the test procedure and to verify proper test performance.

- This test should be used only for the qualitative detection of drugs of abuse in oral fluid.

- This test provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmatory analytical test result. General Considerations for Blood and Other Biological Specimens (GCBMS) has been established as the regulatory confirmation method by the US Food and Drug Administration (FDA). All results and professional judgment should be applied to the test result, particularly when preliminary positive test results are indicated.

- A positive test result is a guide to potential problems and does not provide a conclusive diagnosis.

- A negative test result does not preclude the possibility of drug metabolism and does not rule out the presence of metabolites.

- Limits of the Test

1. This device should be used only for the qualitative detection of drugs of abuse in oral fluid.

2. This test provides a preliminary analytical test result only. This test is intended to confirm the presence of drugs of abuse in oral fluid. The test is not intended as a sole test for the detection of drugs of abuse in oral fluid. The test should be used in conjunction with other testing methods, such as urine drug testing, to confirm the presence of drugs of abuse in oral fluid.

- This test is intended for use with oral fluid specimens only.

- Oral fluid specimens must be collected according to the directions in the specific collection section of this package insert.

- Perform testing immediately after specimen collection.

- 3 specimens to be shipped, pack them in compliance with all applicable regulations for transportation of biological agents.

- This device is intended for use with human oral fluid specimens only.

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