OrAlert™

ORAL FLUID DRUG SCREEN DEVICE PROCEDURE
The information in this presentation is a general overview on performing and interpreting the OrAlert™ Oral Fluid Drug Screen Device.

PRODUCT TRAINING CONTENTS

• TECHNICAL INFORMATION
• PRODUCT OVERVIEW
• SPECIMEN COLLECTION AND TESTING PROCEDURES
• INTERPRETATION OF RESULTS
• ADDITIONAL SUPPORT SERVICES
Technical information

FOR COMPLETE INSTRUCTIONS, LIMITATIONS AND WARNINGS, PLEASE REFER TO THE PACKAGE INSERT (INSTRUCTIONS FOR USE) BEFORE USING THIS SCREENING DEVICE.

The OrAlert™ Oral Fluid Drug Screen Device is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in oral fluid.

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), gas chromatography/tandem mass spectrometry (GC-MS/MS) and liquid chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods.

Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Forensic Use Only devices are intended for use only in drugs of abuse testing for law enforcement purposes.
OrAlert™ overview
OrAlert™ overview

The OrAlert™ Oral Fluid Drug Screen Device is a rapid, oral fluid screening test that can be performed without the use of an instrument.

FEATURES AND BENEFITS

• Rapidly screen up to 7 illicit drugs and prescriptions drugs.
• Improved sensitivity of parent THC.
• Ideal for recent use detection.
• Eliminates need for gender-specific observation and limits adulteration and tampering.
• Read results in 10 minutes.
## Abbreviations and cutoff level

<table>
<thead>
<tr>
<th>DRUG</th>
<th>CUTOFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine (AMP)</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Benzodiazepines (BZO)</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Cocaine (COC)</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Marijuana (THC)</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine (m-AMP)</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Opiates (OPI)</td>
<td>40 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>10 ng/mL</td>
</tr>
</tbody>
</table>
Precautions, Storage, and Stability

PRECAUTIONS:

- For forensic use only.
- Do not use after the expiration date.
- The oral fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

DEVICE STORAGE AND STABILITY

- Store packaged in the sealed pouch at 36-86°F (2-30°C).
- The tests are stable through the expiration date printed on the pouch.
- Test cards must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use beyond the expiration date.
Performing an oral fluid drug screen
Performing an oral fluid drug screen

SPECIMEN COLLECTION AND PREPARATION

• The oral fluid specimen should be collected using the collection device provided with the kit.
• No other collection devices should be used with this assay.
• Collectors have the flexibility of collecting oral fluid at any time of the day.
• Allow the OrAlert™ device to come to room temperature (15-30°C / 59-86°F) prior to testing.
• Instruct the donor not to place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.
Performing an oral fluid drug screen

GATHER ALL NECESSARY TESTING MATERIALS

Materials provided

• One (1) test device
• One (1) OrAlert™ device per pouch
• One (1) package insert
• One (1) saliva collector
• One (1) procedure card
• Tamper evident tape

Required but not provided

• Timer
Performing an oral fluid drug screen

**FOIL POUCH WITH DEVICE**

The foil pouch contains the following information: list of drugs screened, adulterants, catalog number, lot number, and expiration date.

- Test device must remain in sealed pouch until use.
- Do not use beyond the expiration date.
- Do not use if pouch is punctured or not sealed.
Performing an oral fluid drug screen

TESTING PROCEDURE

• Bring the pouch to room temperature (15-30ºC / 59-86ºF) before opening it.

• Remove the test and cap from the sealed pouch and use the test as soon as possible.

• Remove the collector from the sealed pouch and give it to the donor.
Performing an oral fluid drug screen

TESTING PROCEDURE

Instruct the donor to insert the sponge end of the collector into the mouth and actively swab the inside of the mouth and the top of the tongue. As soon as the sponge softens lightly, the donor should gently press the sponge between the tongue and teeth to ensure complete saturation.

The sponge is saturated when no hard spots can be detected. Collect for a total of three (3) minutes before removing the sponge.
Performing an oral fluid drug screen

TESTING PROCEDURE

Remove the collector from the mouth. With the test device on a flat surface, insert the collector into the test device by aligning the notches on the collector with the tracks on the inside of the collection chamber. Push the collector into the chamber and turn the collector clockwise until it is engaged.
Performing an oral fluid drug screen

TESTING PROCEDURE

After 1 minute, rotate the collection chamber counterclockwise and set the timer for 9 minutes.
Interpretation of results
Interpretation of results

READING DRUG TEST RESULTS

• Wait for colored lines to appear.

• Read the drug test results at 9 minutes.

• The test strip within the device includes an internal procedural control (C) that ensures proper device function.

• The control line should form on the (C) line, indicating proper functioning of the test device.

• Do not interpret results after 1 hour.

NOTE: Any line at all in the test area is to be interpreted as negative.
Negative example

NEGATIVE TEST RESULT

• A colored line appears in the Control region (C) and a colored line appears in the Test region (T) next to each drug name or number specific drug test.

• Negative results means the drug concentrations in the urine sample are below the designated cutoff levels for a particular drug tested.

• Any line at all in the test zone is to be interpreted as negative.

NOTE: Any line at all in the test zone is to be interpreted as negative.
The test device provides only a qualitative, preliminary analytical results. Gas chromatography/mass spectrometry (GC-MS), gas chromatography/tandem mass spectrometry (GC-MS/MS) and liquid chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods.
Invalid example

INVALID TEST RESULT

• If a color band is not visible in the Control Region (C) or a color band is only visible in the Test Region (T), the test is invalid.

• Another test should be opened and run to re-evaluate the specimen.

• If test still provides an invalid result, please contact the distributor from whom you purchased the product.

• When calling, be sure to provide the lot number and the catalog number of the test.
Interpreting test results

NEGATIVE
The control line must be colored to indicate the test is valid.
Any visible line, even a faint line, indicates a negative result.

PRELIMINARY POSITIVE
The control line must be colored to indicate the test is valid.
The test area must be white to be considered positive.
Additional testing is necessary to confirm the preliminary positive results. Positive results must be “confirmed” by an alternate method such as GC-MS, GC-MS/MS, or LC-MS/MS.

INVALID
When there is no line in the control line area, the result is invalid.
If an invalid result is obtained repeat the test using a new test device.
Congratulations!
You have completed the training course.

CLOSE WINDOW TO ACCESS QUIZ

You can now take a quiz with 10 questions that represent hypothetical situations for you to analyze. You need to score 100% to pass and receive your Certificate of Completion. Take the quiz as many times as you like to pass. Helpful tips are available for incorrect answers.

For additional information or assistance with this device contact Technical Support at 877-444-0049

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