Oratect®
Oral fluid drug screening device

Better information. Better decisions.
It is important to read the package insert before using the Oratect screening device.

For in vitro diagnostic use only. Professional judgment should be applied to any drug of abuse test result, particularly with preliminary positive results.

The Oratect device is used for screening only. Positive results obtained with this device are presumptive. Additional testing is necessary to confirm the presumptive positive results. Positive results should be confirmed by an alternate method such as GC/MS (Gas Chromatography/Mass Spectrometry) or LC/MS/MS (Liquid Chromatography/Tandem Mass Spectrometry).
Product overview
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The Oratect Oral Fluid Drug Screen Device is a simple one-step test for the detection of drugs of abuse in oral fluid.

Feature and benefits

- FDA 510(k) Cleared to Market
- Screens 6 illicit and licit drugs
- Simple procedure: collect and test in one step—results in five minutes
- Convenient and non-invasive rapid onsite screening
- Eliminates need for cross gender observation
- Reduces sample adulteration or contamination
- Includes transport tube for confirmation testing

25 Oratect ® test devices per box. Includes transport collection tube for confirmation testing.
Drug detection cutoff levels.

<table>
<thead>
<tr>
<th>Drug / Abbreviation</th>
<th>Calibrator</th>
<th>Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine (AM)</td>
<td>d-Amphetamine</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Cocaine (CO)</td>
<td>Cocaine</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Marijuana (TH)</td>
<td>Δ-9-Tetrahydrocannabinol</td>
<td>40 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine (ME)</td>
<td>d-Methamphetamine</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Opiates (OP)</td>
<td>Morphine</td>
<td>40 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PC)</td>
<td>Phencyclidine</td>
<td>10 ng/mL</td>
</tr>
</tbody>
</table>
Device components

- Oratect Oral Fluid Collection Tube (50 mL polypropylene tube for sending presumptive positive specimens for confirmation)
- Foil Pouch (Includes lot and expiration details)
- Oratect Screening Device
NOTE: The desiccant pouches are part of the packaging, they are not a part of the screening device.

Foil pouch and packaging

Precautions:

- Lot number, expiration date, part number and a list of abbreviated drugs screened are located on the foil pouch
- Do not use after the expiration date printed on the pouch
- Do not open the sealed pouch until use
- Store at room temperature 15°-30°C (59°-86°F)

NOTE: The desiccant pouches are part of the packaging, they are not a part of the screening device.
Oral fluid testing supplies and collection procedure
Gather all necessary testing supplies

Materials provided:
- Oratect device
- Package insert/Quick Reference Guide
- Oral Fluid Collection Tube (if needed for confirmation testing).

Chain of custody form:
- On-Site Custody and Control Form (Supplied separately)

Recommended but not provided:
- Timer
On-Site Custody and Control Form can be used for both urine and oral fluid specimens. Use ballpoint pen, press hard, and check all copies for legibility. NOTE: Back page also includes form instructions.
Collecting the specimen
Collecting the specimen

Instruct donor on proper procedure for saliva collection.

Warnings and precautions
Prior to testing, DO NOT place anything in the mouth for at least 10 minutes.

This includes:
- Food
- Drink
- Gum
- Tobacco products (chew or smoke)
- Any other materials

Handle all oral specimens as potentially infectious. Proper handling and disposal methods should be established.
Collecting the specimen

- The test device should remain in its original sealed pouch until ready for use.
- Discard the test device if package is ripped or torn.
- Do not use the test device beyond the expiration date indicated on the foil pouch.
- Bring the pouch to room temperature before opening it.
- Remove device from pouch by tearing at small notch at top of pouch.

Remove screening device from foil pouch.

NOTE: The desiccant pouches are part of the packaging.
Collecting the specimen

- Once removed from the sealed pouch, use the test as soon as possible.
- Remove the cranberry color cap by holding the sides* and pulling gently. This will expose the collection pad.
- Make sure there is a blue line present in each window area indicating an unused device. If there is no blue line, dispose of device and get a new one.

*Make sure when removing the test cap that it is pulled gently from the sides and not from the end so that the pad is not pulled out while removing the cap.
Collecting the sample

- Instruct the donor to hold the device in place with their hand.
- Instruct donor to open mouth and gently rub* the collection pad inside mouth against cheek in a circular motion for approximately 15-20 times.
- Make sure to keep head level.
- Gently rub the pad against the opposite cheek in circular motion for approximately 15-20 times.
- Place collection pad under the tongue for approximately 30 seconds to collect saliva.

*During the swabbing process make sure the test subject does not swab too vigorously. Sometimes test subjects swab so hard that they pull the collection pad loose. Swabbing should be done in a gentle circular motion.
Collecting the sample

- When sufficient amount of saliva is collected the blue lines will move.
  - Repeat steps from previous page until blue lines start to move upward
- Remove from mouth as soon as blue lines move in both of the test windows.
- Re-cap the device.
- Lay device on a flat surface.

Note: The flow of the blue lines should appear in the test windows within 5 minutes. If no flow is observed after 5 minutes in the mouth, discard the device, review procedures of the package insert with the donor and repeat the test using a new device.
Result interpretation
Interpretation of results

- Place the test device horizontally on a clean and level surface with result window facing up.
- Within seconds you will notice a pinkish migration or flow of sample as the test strips start running.
- For each of the test windows, purple-red colored bands should be observed; one band at the control region (C) and one band the specific drug abbreviation (e.g. AM, OP, CO) in the test region.

Lay on flat surface.

Negative for Amphetamine, Opiate and Cocaine.
Interpretation of results

- Read test results at five minutes.
- Do not interpret results after 15 minutes as false results may occur.
- The color of the test band may be slightly darker or lighter than the control band.
- Read each test independently.
- Do not compare color intensity of one test to another.
NEGATIVE
The control line must be colored to indicate the test is valid. Any visible line, even a faint line, indicates a negative result.

POSITIVE
The control line must be colored to indicate the test is valid. The test area must be snow white to be considered positive.
*Additional testing is necessary to confirm the presumptive positive results. Positive results should be “confirmed” by an alternate method such as GC/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.
NEGATIVE = line is present

- For each test, two colored bands should be observed: One in the CONTROL (C) region, one in the specific TEST region. The color of the test band may be slightly darker or lighter than the control band. Any visible band that can be seen is a negative result.

- This means that the oral fluid sample does not contain that particular drug, or that the drug level is lower than the detection level.

- Record negative results in STEP 6 of the Custody and Control Form (supplied separately).
Presumptive positive example

PRESUMPTIVE POSITIVE \(=\) line is not present

- The result is preliminary positive when there is a line in the control region (C) and no line in the test region.
  - Example at right shows a presumptive positive for Amphetamines.

- This means that the oral fluid sample is preliminary positive for that particular drug.

- Record non-negative(s) results in STEP 6 of the Custody and Control Form (supplied separately), and then prepare for a confirmation laboratory test. See section “Preparing specimens for laboratory confirmation.”
Invalid example

INVALID  = control line is not present

- When no colored band appears in the CONTROL (C) region, the test is invalid even if there is a band in the test region.
- Repeat the test with a new device.
Preparing specimens for confirmation
Preparing specimens for lab confirmation.

- If a *presumptive positive* is present, the Administrator will need to collect a second “neat” saliva specimen* by using the Oratect® Oral Fluid Collection Tube for laboratory confirmation testing via GC/MS or LC/MS/MS.

- **DO NOT** send the Oratect® Screening Device to the laboratory.

*2nd collection requires the donor to directly spit into the collection tube.
Sending sample to the lab for confirmation

Collecting a second specimen for confirmation testing.

- Remove cap from Oratect Collection Tube
- Have donor carefully spit into tube several times until half of the bottom cone (~ 2.5 mL) is collected.
- Tightly re-cap sample collection tube, checking for a secure fit.
Sending sample to the lab for confirmation

Labeling and sealing the specimen.

- Locate one (1) security seal (sticker) located on the Custody and Control Form.
  - Collector signs and dates seal.
  - Donor initials seal.

- Collector removes security seal/barcode from Custody and Control Form and places over the tub cap lengthwise.

- Collector will affix one (1) security seal over the cap of the collection tube.

Security seal located on Custody and Control Form (supplied separately)
Packaging specimens for delivery.

- Check the On-Site Custody and Control Form (CCF) and make sure it is completed correctly, and that the security seal has been properly affixed to the oral collection tube.

- Place both the Lab CCF and the sealed Oratect Collection Tube inside the specimen bag and seal. **Do NOT send the test device**

- Place lab specimen bag into the transport bag provided by the lab and seal.

- Place the provided pre-paid FedEx shipping label on outside of transport bag.

- To schedule a pick up, call FedEx at 800.463.3339 or go to www.fedex.com to schedule a pick up.

We recommend using a lab-based saliva drug test for confirmation testing. Call us at 610-509-0567 for details.
Troubleshooting guide
There are typically only three reasons that users may have an issue getting the Oratect to run correctly.

1. There is not enough saliva on the test collection pad to activate the test.

2. The collection pad has become dislodged from the test device or is bent or broken.

3. Flooding of the collection pad.

The following section covers these three topics in detail. For additional assistance contact Technical Support at 800.340.4029.
1. **Not enough saliva on the collection pad.**

   The Oratect® requires approximately .55 mL of saliva to activate the test. To make sure enough saliva is collected on the pad the described collection procedures should be strictly followed.

   - Remove the cap on the collection pad by pulling gently from the sides of the cap. Do not remove the cap by pulling from the end.
   - Gently swab each cheek in a circular motion approximately 15 times with the printing on the device facing the cheek. Advise the test subject to not chew, bite, or suck on the collection pad.
   - Gently swab the top of the tongue approximately 15 times with the printing on the device facing the tongue.
   - Gently swab underneath the tongue approximately 15 times with the printing facing up.
   - Place the device underneath the tongue (like a thermometer) with the head held level for approximately 30 seconds to one minute. Tell the test subject to generate as much saliva in the mouth as possible. When placing the device under the tongue it should be inserted in the mouth only through the collection pad area. Do not insert the device far enough in the mouth to cover any of the test result area.

- Once the blue control line starts to flow on both test strips followed by a pink colored flow tell the test subject to remove the device and replace the cap. Then lay the device on a level surface.
- If the blue lines on both strips do not flow after approx. one minute remove the device and repeat the swabbing process. It is OK to repeat using the same device.
- Read the results after 5 minutes. Results may be read up to 15 minutes.
- There must always be a line in the Control area on both strips by the C. If there is no line in the C area the test is invalid and should be repeated using a new device.
- A line in the test area by each drug name is a negative result. No line in the test area by each drug name is a preliminary positive result.
- Any line no matter how faint should be interpreted as a negative result.
- Do not compare line intensity from one assay to another or from one test device to another.
- The THC result line on the Oratect may be lighter than the lines for other assays. A faint line should still be interpreted as a negative result.
2. **The collection pad is dislodged from the test device or is bent or broken.**

- The collection pad on the Oratect was originally designed to be removed after the test was completed by replacing the cap and pulling the cap from the end. The collection pad was then placed in a vial of buffer solution and transferred to a laboratory for confirmation testing.

- With the FDA 510K Clearance for the Oratect, the confirmation procedure was changed to eliminate sending in the pad in a buffer solution to using the saliva collection confirmation tube now included with each box of Oratect.

- If the collection pad becomes dislodged even slightly from the test device it will interfere with the flow of the specimen onto the device and the test will not run.

- You will not be able to see if the pad is dislodged because it is inside the test device.

- If the test administrator sees no flow of the blue line even though there appears to be sufficient saliva collected the dislodged test pad may be the reason.

- If the test administrator sees one test strip flow and no flow or partial flow on the other strip it is usually an indication that the test pad has been dislodged.

- You can not push the collection pad back into place once it has been dislodged, you will need to repeat using a new device.

- To prevent the collection pad from being dislodged it is important to do the following:
  
a. Make sure when removing the test cap that it is pulled gently from the sides and not from the end so that the pad is not pulled out while removing the cap.

b. During the swabbing process make sure the test subject does not swab too vigorously. Sometimes test subjects swab so hard that they pull the collection pad loose. Swabbing should be done in a gentle circular motion.

c. Make sure the test subject does not chew, bite, or suck on the test pad as any of these actions can cause the pad to come loose.

d. If the test collection pad appears to be bent or broken and does not run even with what appears to be adequate saliva it is likely the test subject has bitten on the pad causing it to be broken and the flow interrupted.

e. If the collection pad is bent or broken the test should be repeated using a new device.
3. Flooding the collection pad.

- It is possible that you can actually get an excess of saliva on the collection pad.

- When there is an excess of saliva flowing to the membrane it may cause the normal reaction process to be circumvented.

- If there appears to be a large amount of saliva on the collection pad and the blue line disappears but no control or test lines appear, the device may be flooded.

- This means the blue lines moved before the collection cycle was completed.

- If the device is flooded the test must be redone using a new device.

- To prevent flooding the test subject should remove the device as soon as the blue lines start to flow followed by the pink flow up each test strip.

**NOTE 1:** A common way to "cheat" an instant saliva drug test is to move or "wiggle" the swab with the tongue or teeth. The donor will make this look accidental. However, by doing wiggling or biting the swab, the swab will move a little and the saliva won't be able to travel up to the test strips. In turn, you'll think the device is defective. Carefully watch the donor to make sure he/she does not bite or wiggle the swab with the tongue. We suggest that you pull apart a device to see how it is made. You'll see how easy it is to dislodge the swab and prevent saliva from moving up to the test strips.

**NOTE 2:** The instant saliva drug test may not have enough saliva to work. If the test does not work after inserting the device in the mouth the first time, reinsert the device up to five times leaving the device under the tongue like a thermometer for 1 minute each time.
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