iScreen® OFD (Oral Fluid Device)
Substance abuse screening device

PRODUCT TRAINING PROCEDURES

For Forensic Use Only.
The information in this presentation is a general overview on using the iScreen® OFD substance abuse screening device.

**Product Training Contents:**

- iScreen OFD overview
- Collection procedure
- Testing procedure
- Reading results
- Sending presumptive positives for confirmation
OFD technical information

It is important to read the package insert before using the OFD screening device.

Screening Results:
The OFD 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).

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

The OFD screening device is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine and their metabolites in oral fluids.

For Forensic Use Only.
Product overview
iScreen® OFD product overview

The iScreen® OFD (Oral Fluid Device) offers you a reliable and affordable saliva drug test solution. Screening devices are now widely available, but few manufacturers offer RTL’s quality, flexibility, and superior support.

FEATURES & BENEFITS

• Tests include: AMP, COC, M-AMP, OPI, PCP and THC
• Eliminates the need for a controlled urine collection site
• Eliminating privacy concerns and same sex administrators
• Ideal for recent use detection
• Change to read at 10 minutes

* See page 8 for abbreviations and cut-off levels
iScreen® OFD components

Blue Cap (Non-Disposable)
Sample Collector Protector (Disposable)
Sponge
Device

Pouch

Sample Port
Security Seal

Oral Fluid Drug Screen Device
Catalog Number: I-DSB-765-011
(COC/mAMP/PCP) + (MTC/OPI/AMP)
LOT: DOAXXXXXXX  EXP: 2010/11
OFD Packaging

Lot number, expiration date, part number and a list of abbreviated* drugs screened on that specific OFD device are located on the back of the foil pouch.

* See page 8 for abbreviations
## iScreen® OFD Cutoff Levels

<table>
<thead>
<tr>
<th>Drug</th>
<th>Target Drug</th>
<th>Cutoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine (AMP)</td>
<td>D-Amphetamine</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Cocaine (COC)</td>
<td>Benzoylecgonine</td>
<td>20 ng/mL</td>
</tr>
<tr>
<td>Marijuana (THC)</td>
<td>11-nor-(\Delta 9)-THC-9 COOH</td>
<td>12 ng/mL</td>
</tr>
<tr>
<td>Methamphetamine (M-AMP)</td>
<td>D-Methamphetamine</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Opiates (OPI)</td>
<td>Morphine</td>
<td>40 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>Phencyclidine</td>
<td>10 ng/mL</td>
</tr>
</tbody>
</table>
Collection procedure
Collect specimen

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

This includes:

- Food
- Drink
- Gum
- Tobacco products
- Any other materials
Collecting specimen

Bring the pouch to room temperature before opening it. Remove the test and Cap from the sealed pouch and use the test as soon as possible.

Remove Sample Collector Protector from the collection Sponge*.

NOTE: The desiccant pouches are part of the packaging, they are not a part of the screening device.

*The Sample Collector Protector can be discarded.
Collecting specimen

Insert Sponge end of collector into the donor’s mouth.

Actively swab the inside of the mouth and tongue with Sponge. As soon as the Sponge softens slightly, gently press the Sponge between the tongue and teeth to ensure complete saturation. The Sponge is saturated when no hard spots can be felt. Collect for at least three (3) minutes before removing Sponge.

Hand the saturated collector over to the tester.
Testing procedure
Gently **plunge** the OFD sponge into the blue cap **3 times**.

Align the Red Arrow on the device with either one of the **White Marks** on the Cap. Insert the collector **vertically** into the Cap and **press down firmly until the Cap reaches the thread**.

Twist the Handle clockwise **180°** to tighten the Cap until the **Red Arrow** lines up with the other **White Mark**.
Testing procedure

Place the test device horizontally on a clean and level surface with result window facing up.

This process will cause the test to begin to run. Within seconds you will notice a pinkish migration or flow of sample as the test strips start running.
Reading results
Result interpretation

Wait for colored lines to appear. Read test results at **10 minutes**. Do not interpret results after 1 hour as false results may occur. **NOTE:** Any line at all in the test area is to be interpreted as negative.
Result interpretation

NEGATIVE
The control line must be colored to indicate the test is valid. Any visible line, even a faint line, indicates a negative result. See example page 19.

POSITIVE
The control line must be colored to indicate the test is valid. The test area must be snow white to be considered positive. See example page 20. *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).

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.

If the problem persists, contact RTL Toxicology Support Services at: (800) 255-2159, option 5.
Presumptive Positive Result

Notice the lines next to the letter C or Control area in both result windows. This indicates the test is valid and working properly.

If no line shows next to that drug, the result has screened positive.
Negative Result

Notice the lines next to the letter C or **Control** area in both result windows. This indicates the test is valid and working properly.

If any line appears, regardless of color intensity, the result is negative.
Invalid Result

If there is no line next to the letter C or Control line after 10 minutes then the test is considered an **INVALID** test result.

If this happens, then the donor must be re-tested.
Additional support services
**Additional support services**

**SENDING SPECIMENS TO THE LABORATORY**  
» Download PDF  
For instruction on how to send presumptive positive specimens to the lab, please review the next document in the training services: “Shipping & Labeling Protocol”.

**COLLECTION AND REPORTING MANAGEMENT**  
» Learn more  
Take advantage of RTL’s powerful collection and reporting system. Schedule donors, manage on-site tests, view reports and route presumptive positive specimens to the lab.

**PRELIMINARY RESULT FORMS**  
» Download PDF  
Log on-site results by downloading a Preliminary Result Form PDF. Printed form pads are available by request. These forms are not lab test request forms (for further confirmation testing).