Oratect® III Oral Fluid Drug Screen Device

Training and Certification Program

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Training and Certification for Test Administrators

The information provided is intended to educate test administrators in the use of the Oratect® III Oral Fluid Drug Screen Device. Please read the following information carefully. A multiple-choice test will be administered once the material has been reviewed.

Intended Use

The Oratect® III Oral Fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of THC (TH), methamphetamine (ME) including MDMA (ecstasy), cocaine (CO), amphetamine (AM), opiate (OP), phencyclidine (PC), benzodiazepines (BZ) in human oral fluid. Oratect® III was developed to detect active drugs-of-abuse present in oral fluid. Studies show that cocaine, opiate, amphetamine, methamphetamine/MDMA, THC, phencyclidine and benzodiazepines are detectable in oral fluid.

The test is intended to be administered by a trained professional. It should not be used without supervision. This product is intended for forensic use only and is not for use in diagnostic procedures.

The Oratect® III Oral Fluid Drug Screen Device provides only preliminary drug test results. For quantitative results or for a confirmation of a presumptive positive drug result obtained by Oratect® III, a more specific alternative method such as GC/MS must be used.

Specific Test Cut Off Concentration

CO	Cocaine	20 ng/ml
ME	Methamphetamine/MDMA	25 ng/ml
TH	THC (Δ9-tetrahydrocannabinol)	40 ng/ml
AM	Amphetamine	25 ng/ml
OP	Opiate	10 ng/ml
PC	Phencyclidine (PCP)	4 ng/ml
BZ	Benzodiazepine	5 ng/ml

Warnings and Precautions

- The Oratect® III Oral Fluid Drug Screen Device is intended for forensic use only and is not for use in diagnostic procedures.
- The test device should remain in its original sealed pouch until ready for use.
- Discard the test device if pouch is ripped or torn.
- Do not use the test device beyond the expiration date indicated on the kit.
- Handle all oral specimens as potentially infectious. Proper handling and disposal methods should be established.

- The Oratect® III Oral Fluid Drug Screen Device pouch should be stored at room temperature (15°-30°C or 59°-86°F).

Oratect® III Oral Fluid Drug Screen Device

The Oratect® III Oral Fluid Drug Screen Device integrates collection and a lateral flow immunoassay screening test for 6 drugs-of-abuse in one single device.

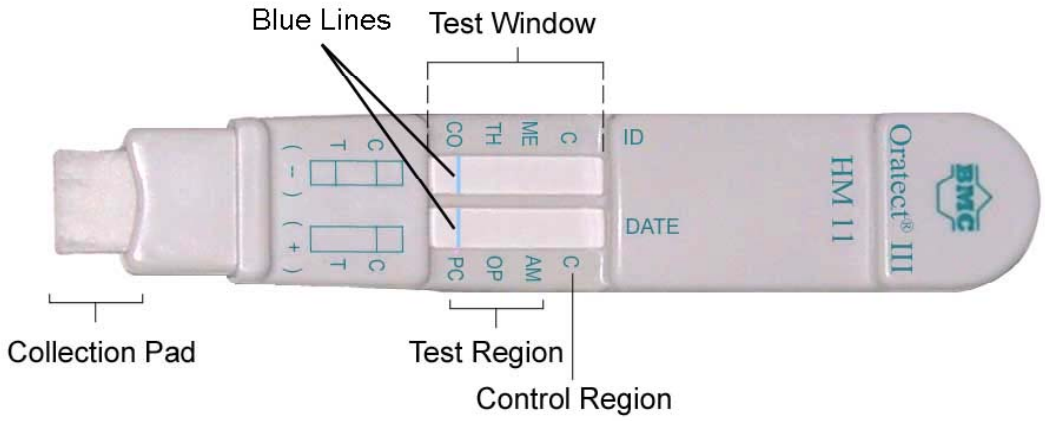

Fig. a Sections of Oratect® III

Test Principle

The Oratect® III Oral Fluid Drug Screen Device is based on a competitive immunoassay procedure in which drug derivatives immobilized on the membrane compete with the drug(s) which may be present in the oral fluid for limited antibody binding sites on the colored colloidal gold antibody conjugate.

During testing, saliva is collected at the collection pad and migrates across the membrane. This is indicated by the movement of the blue lines.

If no drug is present in the oral fluid, the colored colloidal gold antibody conjugate will bind to the drug derivatives on the membrane to form visible bands at specific test regions. **Any presence of a colored band at a specific test region indicates a negative result**.

The absence of a color band at the test region indicates a presumptive positive result for the particular test.

In either case, a color band at the control region (C) must appear and it indicates that the test has performed properly. If the control band does not appear, the test results are invalid and must be repeated with a new device.

Specimen Collection and Handling

IMPORTANT: At least 10 minutes prior to administering the test, instruct the donor not to eat, drink, smoke or chew tobacco products.

Oratect® III Oral Fluid Drug Screen Device Procedure

1. Remove the test device from the sealed pouch.
2. Carefully remove the blue cap by holding the sides and pull gently. This will expose the collection pad.
3. Ensure that the blue line is present in each test window.
4. The oral fluid collection process must be observed. Instruct the subject to hold the top portion of the device (above the two windows). **Do not touch the test window area.**
5. When placing device into the mouth, **keep head level**.
    a. Open mouth and rub the collection pad inside mouth against one cheek in a circular motion several (approximately 15-20) times. **(Fig. b)**
    b. Still keeping head level, rub the collection pad against the opposite cheek in a circular motion several (approximately 15-20) times. **(Fig. b)**

Fig. b Rub the collection pad against each cheek several (approximately 15-20) times.

    c. Rub the collection pad on top of the tongue several (approximately 15-20) times and then underneath the tongue several (approximately 15-20) times. (**Fig c. and Fig d.). Do not chew, suck, bite or bend the collection pad.**

Fig. c Rub the collection pad on top of the tongue several (approximately 15-20) times.

Fig. d Rub the collection pad underneath the tongue several (approximately 15-20) times.

6. Place the collection pad underneath the tongue to collect saliva. Instruct the donor to hold the device in place with their hand.
7. The flow of the blue lines indicates the collection of a sufficient amount of saliva.
8. If blue lines are present after placing the collection pad underneath the tongue for 30 seconds, repeat the instructions in steps 5 and 6 until the blue lines flow. Remove the device from mouth as soon as the blue lines start moving at both test windows.
   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 4-7 above with the donor and repeat the test using a new device.
9. Re-cap the device, lay on a flat surface and **read results in 5 minutes after removing device from mouth. Do not read results after 30 minutes.**

Interpreting Test Results

Negative Results

For each drug test, two (2) colored bands should be observed in the result window; one band at the control region (C) and a band at the specific drug abbreviation (i.e. AM, OP, PC) in the test region (T).

The color of the test band may be slightly darker or lighter than the control band. Any band that can be seen visually, no matter how faint, is a **negative** result. Read each test independently. Do not compare color intensity of one test to another.

In the **Fig. e** below, the oral fluid sample is negative for Amphetamine, Opiates and Cocaine **because bands are visible in the AM, OP, and CO test regions**.

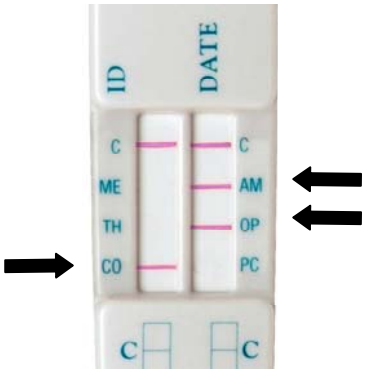

Fig. e Example of negative test results

Presumptive Positive Results

When the control band is visible in the control region (C) and **no** band appears at the specific test region (T), the result is **presumptive positive** for that particular drug. In **Fig. f** below, the oral fluid sample is presumptive positive for Methamphetamine/MDMA **because there is no band visible in the test region of ME.**

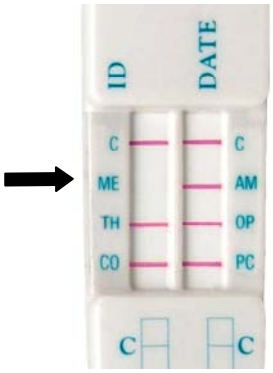

Fig. f Example of presumptive positive test results

Invalid Results

When **no** band appears in the control (C) region, **the test is invalid** regardless of the test results in the test region. If the test is invalid, check testing procedures, and samples. **Repeat the test using a new device.** In **Fig. g** below, the test is invalid because there are no colored bands in the control regions.

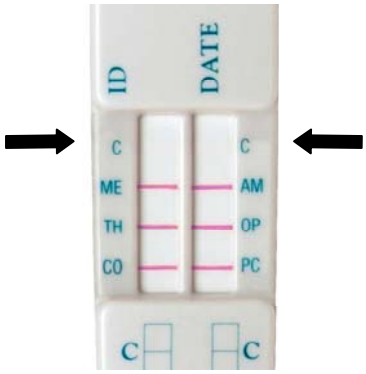

Fig. g Example of <u>invalid</u> test results

<u>Important</u>: Read each test independently. Do not compare color intensity of one test band to another. When a faint color band for a specific test is obtained in the test region of the test window, the sample should be considered negative. Results are stable and may be interpreted for up to 30 minutes after the control bands (C) form. The Oratect® III Oral Fluid Drug Screen Device provides qualitative results for the presence of drug(s) at specified cut-off concentration(s). For confirmation of a presumptive positive result, a more specific quantitative method (i.e. Gas Chromatography/Mass Spectrometry) must be used.

Specimen Collection and Handling for Confirmation

- After reading the test results, re-attach the blue cap by sliding the collection pad inside the blue cap and gently pushing the cap in place. Make sure not to damage or distort the collection pad.
- Detach the collection pad with the blue cap by pinching the cap on the pad and pulling gently. The collection pad should easily fall into the blue cap.
- Drop the collection pad into the confirmation vial of buffer supplied in the kit.
- Send vial along with appropriate chain-of-custody document to your approved laboratory for confirmatory testing. (Chain-of custody documents provided by laboratory)

Limitations of the Procedure

- The assay is designed for use with human oral fluid only.
- Presumptive positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication.
- Technical errors as well as other substances in certain foods and medication may interfere with the test and cause false results.
- If a drug/metabolite is found present in the oral fluid, the assay does not indicate frequency of drug use nor does it distinguish between drugs-of-abuse and certain foods and/or medications.

THIS COMPLETES THE ORATECT® III TRAINING PROGRAM. TO BECOME CERTIFIED AS A TEST ADMINISTRATOR FOR THE DEVICE, YOU MUST COMPLETE THE FOLLOWING QUIZ WITH A MINIMUM SCORE OF 80%.

IF YOU HAVE ANY QUESTIONS OR WOULD LIKE TO SPEAK TO CUSTOMER SUPPORT, CALL US AT 1-888-882-7739 OR E-MAIL info@cliawaived.com or FAX:(801) 720-7568