OratectPlus™ Oral Fluid Drug and Alcohol Screen Device

Training and Certification Program

OratectPlus™ Oral Fluid Drug and Alcohol Screen Device

Training and Certification for Test Administrators

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

Intended Use

The OratectPlus™ Oral Fluid Drug and Alcohol 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) and benzodiazepines (BZ) in human oral fluid. In addition, it is a one-step enzymatic color test for the qualitative detection of alcohol in human oral fluid. OratectPlus™ was developed to detect active drugs-of-abuse present in the oral fluid. Studies show that cocaine, opiate, amphetamine, methamphetamine/MDMA, phencyclidine, benzodiazepines, THC and alcohol 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 OratectPlus™ Oral Fluid Drug and Alcohol Screen Device provides only preliminary drug test results. For quantitative results or for a confirmation of a presumptive positive drug test result obtained by OratectPlus™, a more specific alternative method such as GC/MS must be used. Presumptive positive alcohol results should be confirmed either with a breathalyzer or a blood test.

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
AL	Alcohol	≥ 0.02% B.A.C.

Warnings and Precautions

- The OratectPlus™ Oral Fluid Drug and Alcohol 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 OratectPlus™ Oral Fluid Drug and Alcohol Screen Device pouch should be stored at room temperature (15°-30°C or 59°-86°F) and not to exceed 30°C or 86° F.

OratectPlus™ Oral Fluid Drug and Alcohol Screen Device

The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device integrates collection and a lateral flow immunoassay screening test for 6 drugs-of-abuse plus alcohol in one single device.

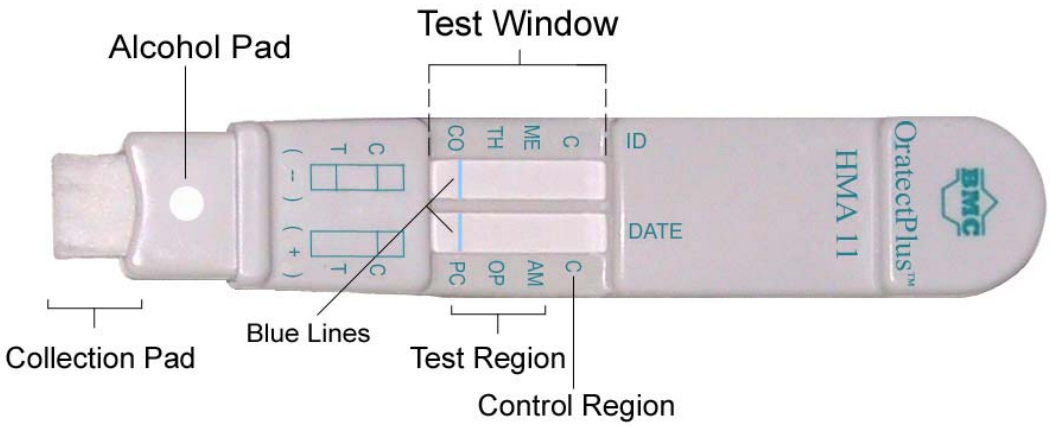


Fig. a Sections of OratectPlus™

Test Principle

The OratectPlus™ Oral Fluid Drug and Alcohol 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 line.

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.

During testing, oral fluid collects on the alcohol pad and saturates it. The alcohol pad is coated with enzymes which turns shades of green and blue on contact with alcohol in the oral fluids.

If alcohol is not present in the oral fluid, the alcohol pad will remain white or cream colored because there is no alcohol in the oral fluid to react with enzymes to start the color reactions.

If alcohol is present in the oral fluid, the alcohol pad changes to a green or blue color because the alcohol reacts with the enzyme alcohol oxidase to produce an aldehyde and a peroxide. The peroxide then reacts with the enzyme peroxidase in the presence of a hydrogen donor to produce a blue color. Therefore, the presence of a green or blue color in the alcohol pad window indicates a presumptive positive result for alcohol.

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.

OratectPlus™ Oral Fluid Drug and Alcohol Screen Device Procedure

1. Remove the test device from the sealed pouch.
2. Carefully remove the clear cap by holding the sides and pulling gently. This will expose the collection pad and a round alcohol pad.
3. Ensure that there is a blue line present in each test window.
4. Observe the alcohol-pad. The pad should be a light cream color. If it is dark tan in color or otherwise discolored, this device should not be used.
5. 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.**
6. 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)

7. Place the collection pad underneath the tongue to collect saliva. Instruct the donor to hold the device in place with their hand.

8. The flow of the blue lines indicates the collection of a sufficient amount of saliva. If blue lines are still present after placing the collection pad underneath the tongue for 30 seconds, repeat steps 6 and 7 until the blue lines flow.

   Note: the flow of the blue lines should appear in the test window within 5 minutes. If no flow patterns are observed after 5 minutes in the mouth, discard the device, review procedures 3-7 with the donor and repeat using a new device.

9. Re-cap the device, lay on a flat surface and read results:
   (a) Read **alcohol test** at **5 minutes** after removing device from the mouth. **Do not read results after 10 minutes.**
   (b) Read **drug tests** at **5 minutes** after removing device from mouth. **Do not read results after 30 minutes.**

Interpreting Test Results

Alcohol Test Results

Alcohol Negative Result

When the alcohol pad shows no color change (remains white or cream colored) the results should be interpreted as negative (no alcohol present). In **Fig. e** below, the oral fluid sample is negative for alcohol **because there is no color change on the alcohol pad.**

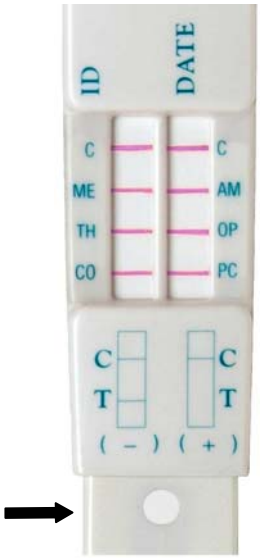


Fig. e Example of <u>negative</u> alcohol test

Alcohol Presumptive Positive Result

When the alcohol test produces a color change to green or blue the test result is presumptive positive. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray. In **Fig. f** below, the oral fluid sample is presumptive positive for alcohol **because there is a color change (green/blue to dark green) from the alcohol pad.**

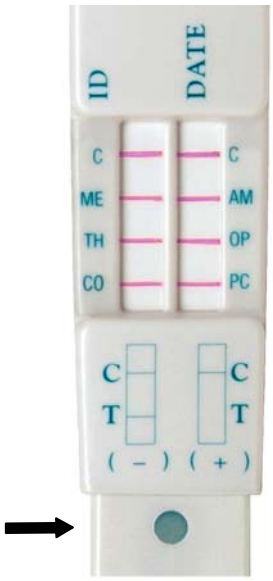


Fig. f Example of <u>presumptive positive</u> alcohol test

Invalid Test Results

As seen in **Fig. g** below, a result where the outer edges of the alcohol pad produce a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid.

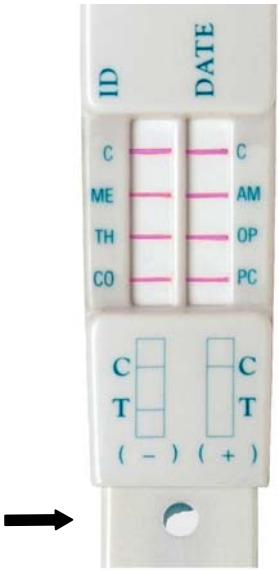


Fig. g Example of <u>invalid</u> alcohol test

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

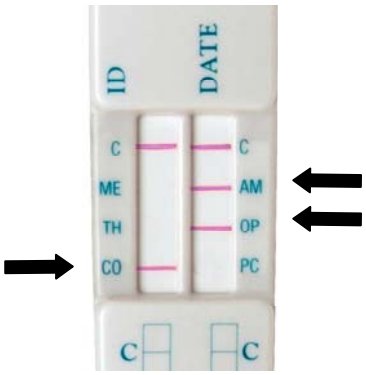


Fig. h Example of negative test results

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. i** below, the oral fluid sample is presumptive positive for Methamphetamine/MDMA **because there is no band visible in the test region of ME.**

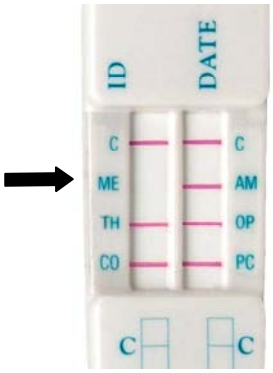


Fig. i Example of presumptive positive test results

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. j** below, the test is invalid because there are no colored bands in the control regions.

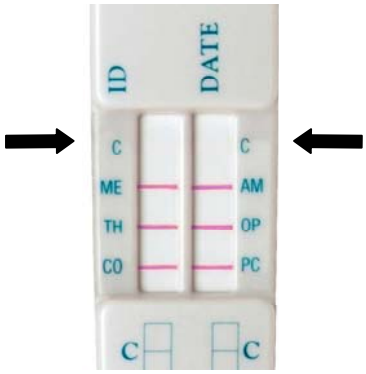


Fig. j Example of <u>invalid</u> test results

<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 OratectPlus™ Oral Fluid Drug and Alcohol 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 clear cap by sliding the collection pad inside the clear cap and gently pushing the cap in place. Make sure not to damage or distort the collection pad.
- Detach the collection pad with the clear cap by pinching the cap on the pad and pulling gently. The collection pad should easily fall into the clear 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)
- To confirm presumptive positive alcohol test results a breathalyzer or blood test should be used.

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 ORATECTPLUS™ 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

OratectPlus™ Certification Test

Instructions: This is a multiple-choice test. Read the questions completely before choosing the best answer. Click on the radio button that corresponds to the best answer. You must complete the test with a score of 80% or better to become certified.

* Note that Name, Organization, Address and Email are required fields. Your test will not be evaluated unless these fields are populated and depending on your browser settings, your answers may be lost if you try to submit without filling out the required fields.

*Name

*Organization

Address:
*No.& Street

*City *State *Zip

*Email

*Phone

Fax:

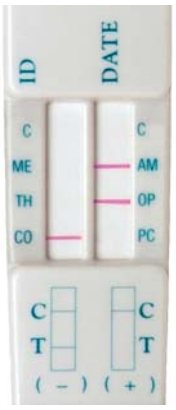
1. The OratectPlus™ Oral Fluid Drug & Alcohol Screen Device provides for the detection of
   - a. 5 drugs plus alcohol in oral fluid
   - b. 4 drugs plus alcohol in in urine
   - c. 6 drugs plus alcohol in oral fluid
   - d. none of the above

2. OratectPlus™ provides _____ drug test results.
   - a. preliminary
   - b. qualitative
   - c. quantitative
   - d. both a and b are correct

3. The absence of a colored band in the control (C) region of the OratectPlus™ device means the test
   - a. result is negative
   - b. result is presumptive positive
   - c. result is invalid
   - d. should be rerun

4. The presence of a colored band at a specific test and a colored band at control (C) region means the test is
   - a. invalid
   - b. negative for that particular drug
   - c. presumptive positive
   - d. wrong

5. Interpret the following test. The test is



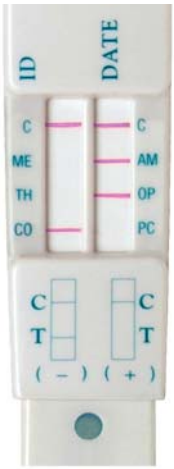
a. presumptive positive for PC, CO, and ME

b. negative for OP and AM

c. invalid

d. negative for ME and PC

6. Interpret the following test. The test is



a. invalid

b. negative for CO, OP, and AM

c. presumptive positive for TH, PC, ME and Alcohol

d. both b and c are correct

7. When testing the device, the test administrator should tell the donor to

a. rub the collection pad on top of the tongue several (approximately 15-20) times, then underneath the tongue several (approximately 15-20) times

b. place the device underneath the tongue for 30 seconds

c. rub the collection pad inside the mouth against the cheek in circular motion several (approximately 15-20) times, then repeat with other cheek several (approximately 15-20) times

d. all of the above

8. The device should be removed from the mouth as soon as the blue lines flow at both test windows. If the flow does not appear in ___ _____, repeat the full procedure again.

a. 30 seconds

b. 2 minutes

c. 5 minutes

- d. 8 minutes

9. Once the device is removed from the donor's mouth, the device should be capped and read. The alcohol result should be read in _____. The drug result should be read in _____.

- a. 2-4 minutes; 2-7 minutes
- b. 15-20 minutes; 15-20 minutes
- c. 5-10 minutes; 5-30 minutes
- d. 6-8 minutes; 6-30 hours

10. The test administrator should tell the individual

- a. not to bite, chew, suck or bend the collection pad
- b. not to touch the test window at any time
- c. to hold the head level at all times while performing the test
- d. all of the above

Submit Test