BRANAN MEDICAL CORPORATION

Product Training & Certification

Oratect® III

Oral Fluid Drug Screen Device

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Oratect® III Oral Fluid Drug Screen Device

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

Oratect® III is a rapid, one-step, onsite, oral fluid device for the qualitative detection of drugs of abuse in human oral fluids. The Oratect® III drug-testing device is easy to administer, reduces the possibility of adulteration, and provides results within five minutes.

Oratect® III was developed using lateral flow immunoassay technology to detect active drugs of abuse present in oral fluid. Studies indicate that drugs such as marijuana, cocaine, opiate, amphetamine, methamphetatmine/ecstasy, phencyclidine, benzodiazepine and alcohol are detectable in oral fluid.

Oratect® III should be administered only by a trained professional. Oratect® III should not be used without supervision. The Oratect® III is intended for **forensic use only** and is not for use in diagnostic procedures.

Specific Test Cut Off Concentration

Oratect® III tests for the following drugs of abuse:

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

The Oratect® III provides only a preliminary screening test result. For a quantitative result or to confirm presumptive positive results obtained by Oratect® III, a more specific alternative method must be used. The Substance Abuse Mental Health Sources (SAMHSA) and the National Institute on Drug of Abuse (NIDA) have established Gas Chromatography/Mass Spectrometry (GC/MS) as the preferred confirmatory method.

Warnings and Precautions

- Oratect® III is intended for forensic use only and is not for use in diagnostic procedures.
- The Oratect® III 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 pouch should be stored at room temperature (15°-30°C or 59°-86°F).

Test Device Regions

Oratect® III integrates collection and a lateral flow immunoassay screening test for 6 drugs-of-abuse in one single device.

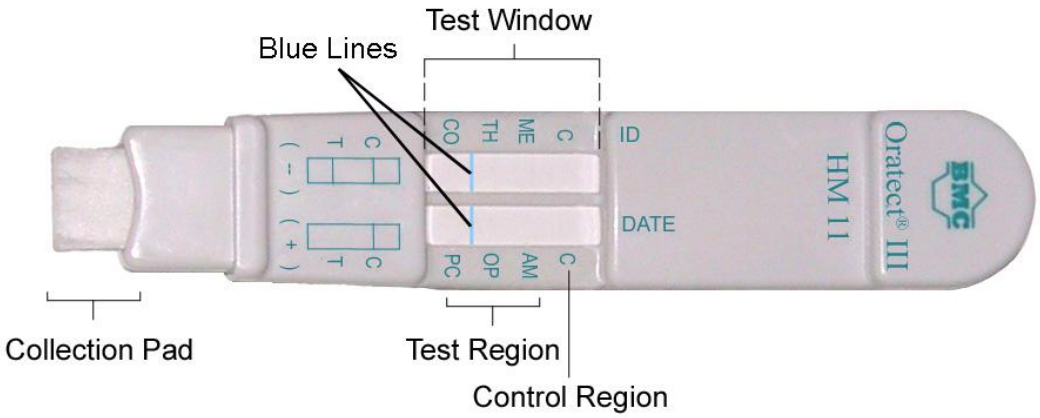


Fig. a Sections of Oratect® III

Test Principle

Oratect® III 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 the 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 indicating 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: Instruct the donor not to eat, drink, smoke or chew tobacco products at least 10 minutes prior to the administration of the test.

Procedures

1. Remove the test device from its sealed pouch.

2. Carefully remove the blue cap by holding both sides and pulling gently. This will expose the collection pad.

3. Ensure the presence of a blue line in each test window.

4. The oral fluid collection process must be observed. Instruct the donor to hold the top portion of the device (above the two windows). **Ensure that the donor does not touch the test window area.**

5. Instruct donor to **keep their head level** when placing device into their mouth.
    a. Instruct donor to rub the collection pad inside their mouth against one cheek in a circular motion 15-20 times. **(Fig. b)**
    b. Instruct donor to rub the collection pad against their opposite cheek in a circular motion 15-20 times. **(Fig. b)**

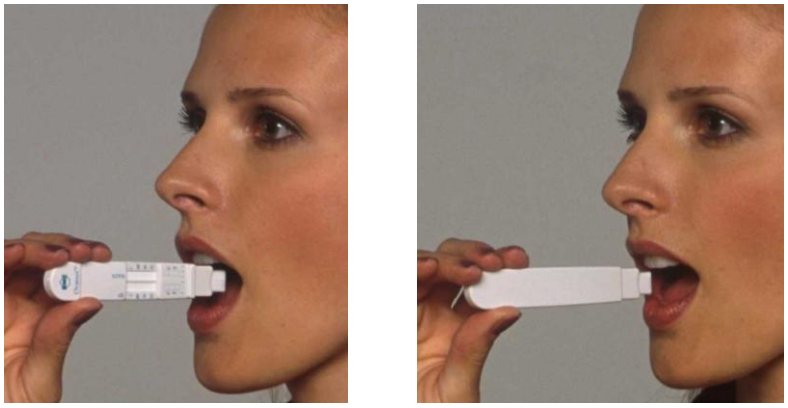


Fig. b Rub the collection pad against each cheek several (approximately 15-20) times.

c. Instruct donor to rub the collection pad on top of their tongue 15-20 times and then underneath the tongue 15-20 times. (**Fig c. and Fig d.) Advise donor not to chew, suck, bite or bend the collection pad.**

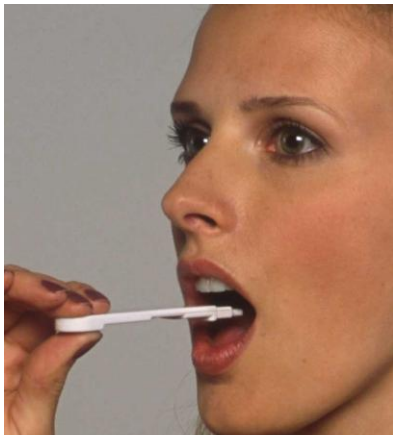


Fig. c Rub the collection pad on top of the tongue several (approximately 15-20) times.

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

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

6. Once the blue lines begin to flow, have donor remove device from their mouth, re-cap the device, and lay on a flat surface.

7. The flow of the blue lines indicates the collection of a sufficient amount of saliva. If the blue lines are still present after placing the collection pad underneath the tongue for 30 seconds, have the donor repeat step 5 until the blue lines flow.

   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 the collection procedures with the donor and repeat the test using a new device.

8. The test results should be interpreted **5 minutes** after removing device from mouth. See package insert.

Interpreting Test Results:

Negative Results

For each drug test, two (2) colored bands should be observed in the test 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.

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

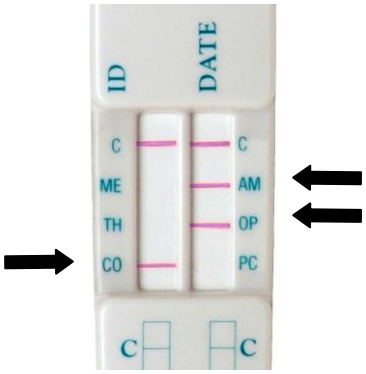


Fig. e Example of negative test results

Presumptive Positive Results

When the control band is visible in the control region (C) and **no** band appears at the specific test region, the result is **presumptive positive** for that particular drug.

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

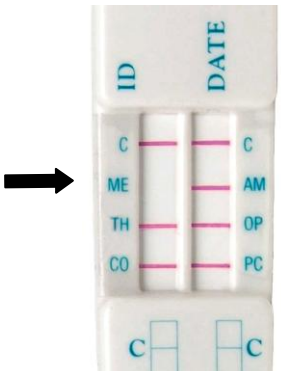


Fig. f Example of presumptive positive test results

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.

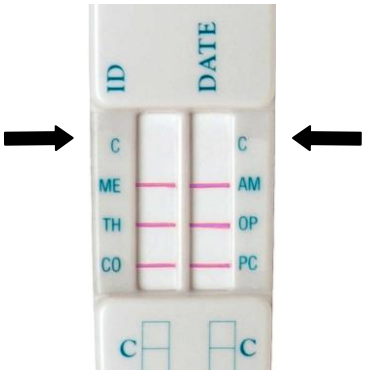


Fig. g Example of <u>invalid</u> test results

<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. Oratect® III provides qualitative results for the presence of drug(s) and alcohol at specified cut-off concentration(s). For confirmation of a presumptive positive result, a more specific method (i.e. Gas Chromatography/Mass Spectrometry) must be used.

Specimen Collection and Handling for Confirmation

1. 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.
2. 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.
3. Drop the collection pad into the confirmation vial of buffer supplied in the kit.
4. 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 and/or alcohol and do not indicate or measure intoxication.
- Technical or procedural errors as well as other substances in certain foods and medication may interfere with the test and cause false results

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 1-866-468-3287/949-598-7166 OR E-MAIL INFO@BRANANMEDICAL.COM.

Oratect® III Certification Test

Instructions: This is a multiple-choice test. Read the questions completely before choosing the best answer. Write your answers on the sheet provided (p. 12).

1. The Oratect® III Oral Fluid Drug Screen Device provides for the detection of

   a. 5 drugs in oral fluid
   b. 4 drugs in urine
   c. 6 drugs in oral fluid
   d. none of the above

2. Oratect® III 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 Oratect® III device means the test

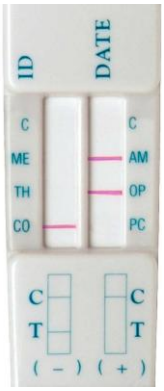
   a. result is negative
   b. result is presumptive positive
   c. result is invalid
   d. none of the above

4. The presence of a colored band at a specific test and a colored band at control (C) region means the test is

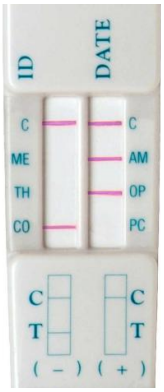
   a. invalid
   b. negative for that particular drug
   c. presumptive positive
   d. wrong

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, AM
   c. presumptive positive for TH and PC, ME
   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 in both test windows. If the blue lines are still present after placing the collection pad underneath the tongue for _____, repeat the collection procedure (step 5) until the blues lines flow.

   a. 30 seconds
   b. 2 minutes
   c. 4 minutes
   d. 8 minutes

9. Test results can be interpreted up to

   a. 1 hour
   b. See package insert for current read time for interpretation of test results
   c. In afternoon
   d. Next day

10. The test administrator should tell the donor

   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

Oratect® III Certification Test Result Sheet

Please enter your answers in the spaces below. Print your name, organization, address, telephone, fax, and e-mail. A certificate will be sent to you if you achieve a score of 80% or higher. Good Luck!

Name _____

Organization _____

Address_____

City, State, Zip Code_____

Telephone_____

Fax_____

E-mail_____

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Answers:

Question 1 _____ Question 6 _____

Question 2 _____ Question 7 _____

Question 3 _____ Question 8 _____

Question 4 _____ Question 9 _____

Question 5 _____ Question 10 _____