



Oratect® III Oral Fluid Drug Screen Device
ME/TH/CO/AM/OP/PC or BZ
Catalog No. HM11 and HM12

Intended Use

The Oratect® III Oral Fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of methamphetamine, MDMA, THC, cocaine, amphetamine, opiates, phencyclidine or benzodiazepines in human oral fluid. The Oratect® III Test detects these drugs at the following cut-off concentrations:

Table with 3 columns: Drug Abbreviation, Drug Name, and Concentration. Rows include ME (d-Methamphetamine/MDMA), TH (Delta-9-Tetrahydrocannabinol), CO (Cocaine), AM (d-Amphetamine), OP (Morphine), PC (Phencyclidine), and BZ (Diazepam).

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 a quantitative result or for a confirmation of a presumptive positive result obtained by the Oratect® III Oral Fluid Drug Screen Device, a more specific alternative method such as GC/MS or LC/MS must be used.

Summary and Explanation

Illegal drug consumption contributes to many accidents, injuries and medical conditions. Screening individuals for drugs of abuse is an important method in identifying those who may cause harm to themselves and to others.

Oratect® III Oral Fluid Drug Screen Device is developed to detect active drugs-of-abuse present in saliva. Studies on methamphetamine, MDMA, cocaine, opiate, amphetamine, phencyclidine, benzodiazepine and cannabinoid show that all of these drugs are detectable in oral fluid. Oratect® III Oral Fluid Drug Screen Device is designed to integrate oral fluid collection and lateral flow immunoassay screen testing for drugs-of-abuse in one single device.

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 oral fluid for limited antibody binding sites on the colored colloidal gold antibody conjugate. During testing, oral fluid is collected at the collection pad and migrates across the membrane. 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. Therefore, the presence of a purple-red band at a specific test region indicates a negative result. If any drug(s) is (are) present in the oral fluid, it competes with the immobilized drug conjugate for limited antibody binding sites of the colored colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug derivative on the membrane. Therefore, the absence of a purple-red band at the test region indicates a presumptive positive result for that particular test.

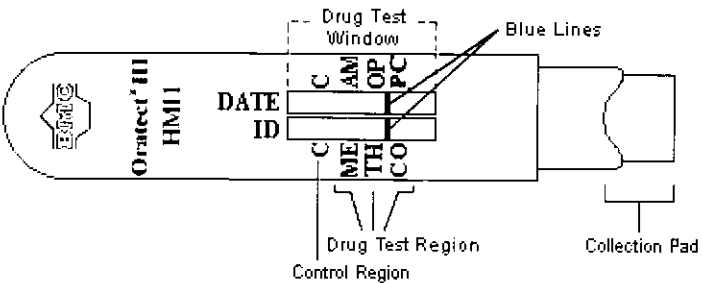


Fig. a Detail regions of Oratect® III Oral Fluid Drug Screen Device

The presence of a blue line in each window indicates that the device is unused. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. A control band at the control region (C) indicates the test has performed properly. This control band should always appear regardless of the presence of drug or metabolite.

Reagents

The Oratect® III Oral Fluid Drug Screen Device contains two membrane strips and a collection pad. Each strip consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad.

Membrane: ME/TH/CO test strip: Methamphetamine, THC and Cocaine-protein conjugates are coated onto specific region on the membrane known as the "Test Region".

AM/OP/PC or AM/OP/BZ test strip: Amphetamine, Morphine, Phencyclidine or Amphetamine, Morphine, Benzodiazepine protein conjugates are coated onto the test region of the membrane.

Colloidal Gold Conjugate Pad: The colloidal gold conjugate pad for the ME/TH/CO test strip contains anti-methamphetamine, anti-THC and anti-cocaine antibody colloidal gold conjugates coated onto a fibrous pad. The colloidal gold conjugate pad for the AM/OP/PC or AM/OP/BZ test strip contains anti-amphetamine, anti-morphine, anti-phencyclidine or anti-amphetamine, anti-morphine, anti-benzodiazepine antibody colloidal gold conjugates.

Collection Pad: The collection pad consists of an absorbent material.

Materials Provided

Each Oratect® III Oral Fluid Drug Screen Device kit contains:

- 1. 1 Package Insert.
2. 1 Reference Guide.
3. 25 test devices. Each device consists of a plastic holder and a detachable cap. The devices are packaged individually in a foil pouch with a desiccant.
4. 1 plastic vial containing buffer for confirmation test.

Materials Required but Not Provided

- Timing device

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 package is ripped or torn.
• Do not use the test device before the expiration date indicated on the kit.
• Handle all oral specimens as potentially infectious. Proper handling and disposal methods should be established.

Product Storage

The Oratect® III Oral Fluid Drug Screen Device pouch should be stored at room temperature (15°-30°C). Do not open pouch until ready to perform the assay.

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.

Test 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 donor to hold the top portion of the device (above the test windows).
5. When placing device into the mouth, keep head level.
a. Open mouth and rub the collection pad inside mouth against one cheek gently in a circular motion several (approximately 15-20) times. (Fig. b)
b. Still keeping head level, gently rub the collection pad against the opposite cheek in a circular motion (approximately 15-20) several times. (Fig. b)

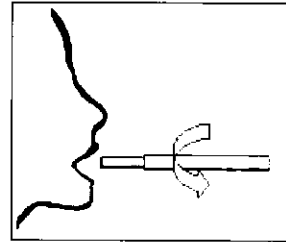


Fig. b Gently rub the collection pad against each cheek several (approximately 15-20) times.

- c. Rub the collection pad on top of the tongue several 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.

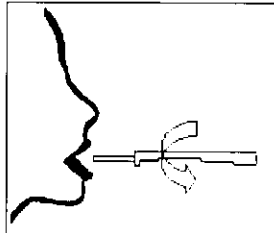


Fig. c Gently rub the collection pad on top of the tongue several (approximately 15-20) times.

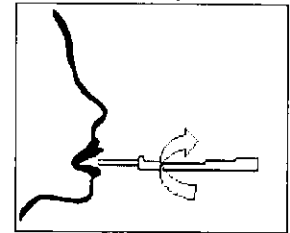


Fig. d Gently rub the collection pad underneath the tongue several (approximately 15-20) times.

- Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with their hand.
- The flow of the blue lines indicates the collection of a sufficient amount of saliva. 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.

- Re-cap the device, lay it 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 of the test windows, purple-red colored bands should be observed; one band at the control region (C) and one band at the specific drug abbreviation (e.g. AM, OP, CO) in the test region. See example Fig. e.

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, Opiate and Cocaine **because bands are visible in the AM, OP, and CO test regions.**

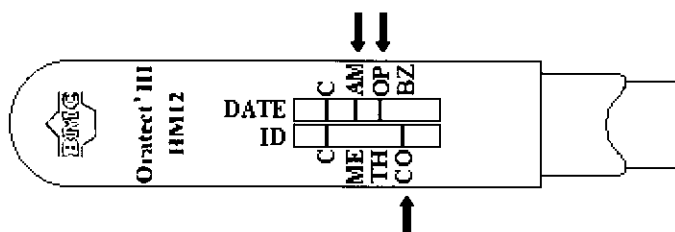


Fig. e. Example of Negative Test Results

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 a **presumptive positive** for that particular drug. In Fig. f below, the oral fluid sample is presumptive positive for Phencyclidine, Methamphetamine (or MDMA) and THC **because no bands are visible in the test regions of PC, ME, and TH.**

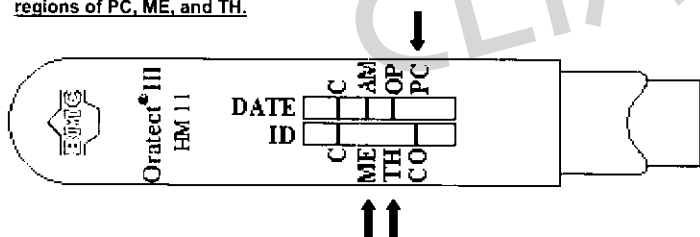


Fig. f. Example of Presumptive Positive Test Results

Invalid Results

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

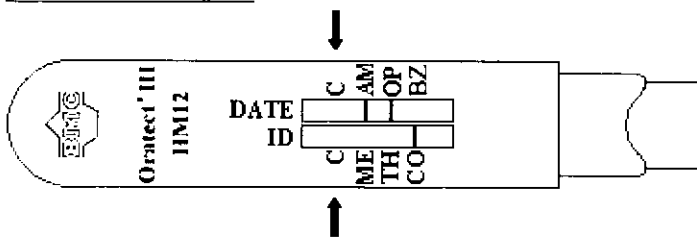


Fig. g. Example of Invalid Test Results

Important: Read each test independently. Do not compare color intensity of one test band to another. When a faint purple-red band for a specific test is obtained in the test region along with the presence of the control line (C), the sample should be considered negative. The Oratect[®] III Oral Fluid Drug Screen Device only 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 (GC/MS or LC/MS) must be used.

Specimen Collection & Handling for Confirmation Testing

- For device with any presumptive positive results, the collection pad should be removed and sent for confirmation test.
- Detach the collection pad with the blue cap by pulling. Be sure not to damage or distort the collection pad.
- Place the collection pad into the enclosed confirmation vial.
- Recap the vial and send it to a lab for confirmatory testing (Specimen should be stored at 15-30°C and tested within 2 weeks of collection).
- Follow standard chain of custody procedures.

Quality Control

The Oratect[®] III Oral Fluid Drug Screen Device provides two built-in control bands at the control regions (C) to indicate that the test has performed properly. These control bands should always appear regardless of the presence of drugs. The flow of the blue lines indicates that a sufficient amount of oral fluid has been collected. The presence of the purple-red bands in the control regions verifies that proper flow was obtained. If the control bands do not appear, the test device should be discarded.

Limitations of Procedure

- The assay is designed for human oral fluid use only.
- Positive results only indicate the presumptive presence of drugs and do not indicate or measure intoxication.
- Technical or procedural errors as well as substances in certain foods and certain medications may interfere with the test and cause false results.

Performance Characteristics

Precision

For each specific drug test, artificial oral fluid solution was spiked with a drug standard at various concentrations (0%, 50%, 200% and 300%). For each concentration, a total of 20 tests were performed to validate the test performance. The results for each drug of the Oratect[®] III Oral Fluid Drug Screen Device Tests are summarized below:

Drug Test	Total # of Test/ Concentration	Concentration							
		0%		50%		200%		300%	
		-	+	-	+	-	+	-	+
ME	20	20	0	20	0	0	20	0	20
MDMA	20	20	0	20	0	0	20	0	20
TH	20	20	0	20	0	1	19	0	20
CO	20	20	0	20	0	0	20	0	20
AM	20	20	0	20	0	0	20	0	20
OP	20	20	0	20	0	0	20	0	20
PC	20	20	0	20	0	0	20	0	20
BZ	20	20	0	20	0	0	20	0	20

Specificity

The specificity study for each drug test was evaluated by adding structurally related compounds to artificial oral fluid solution. The results are expressed as the amount of the compound, in ng/ml, that produced a positive result.

Drug Test	Approximate Concentration (ng/ml)	Approximate % Cross Reactivity
ME/MDMA		
Desipramine	10000	0.25%
d,l-Ephedrine	1000	2.5%
1R, 2S l-Ephedrine	1000	2.5%
p-Hydroxymethamphetamine	1000	2.5%
MDEA	300	8.3%
MDMA	25	100%
d,l-Methamphetamine	30	83%
d-Methamphetamine	25	100%
l-Methamphetamine	500	5%
Methoxyphenamine	2500	1%
Phenylephrine	5000	0.5%
d-Pseudoephedrine HCl	5000	0.5%
Trimethobenzamide	4000	0.6%
TH		
Cannabinol	80	50%
Δ-8-tetrahydrocannabinol	100	40%
Δ-9-tetrahydrocannabinol	40	100%
11-nor-Δ-8-THC-9-COOH	10	400%
11-nor-Δ-9-THC-9-COOH	10	400%
11-hydroxy-Δ-9-THC	400	10%
CO		
Benzoylcocaine	18	110%
Cocaine	20	100%
Ecgonine	5000	0.4%

Drug Test	Approximate Concentration (ng/ml)	Approximate % Cross Reactivity
AM		
d-Amphetamine	25	100%
d,l-Amphetamine	40	62.5%
l-Amphetamine	800	3.2%
d,l-p-Chloramphetamine	200	12.5%
MDA	40	62.5%
MDEA	100	25%
Phentermine	100	25%
β-Phenylethylamine	8000	0.3%
Tyramine	8000	0.3%
OP		
6-Acetylcocaine	20	50%
6-Acetylmorphine	12	83%
Cocaine	10	100%
Dihydrocodeine	10	100%
Ethyl morphine	60	17%
Heroin	15	67%
Hydrocodone	60	17%
Hydromorphone	70	14%
Morphine	10	100%
Morphine-3-beta-D-Glucuronide	25	40%
Nalorphine	100	10%
PC		
Phencyclidine	4	100%
BZ		
Alprazolam	4	125%
Bromazepam	4	125%
Chlordiazepoxide	50	10%
Clobazam	10	50%
Clonazepam	20	25%
Delorazepam	5	100%
Diazepam	5	100%
Estazolam	3	167%
Flunitrazepam	8	63%
Flurazepam	10	50%
Lorazepam	10	50%
Lormetazepam	15	33%
Nitrazepam	4	25%
Nordiazepam	3	67%
Oxazepam	5	100%
Prazepam	10	50%
Temazepam	5	100%
Triazolam	10	50%

Interference

The following compounds were spiked into artificial oral fluid solution and found not to cross-react with the Oratect[®] III Oral Fluid Drug Screen Device when tested at concentration of 10µg/ml (10,000ng/ml)

Acetaminophen	Butalbital
Acetoacetic acid lithium salt	Butethal
Acetone	Caffeine
Acetylsalicylic acid	Cannabinol (except TH assay)
6-Acetylcocaine (except OP assay)	Cannabidiol
6-Acetylmorphine (except OP assay)	Chloral Hydrate
Albumin	Chlordiazepoxide (except BZ assay)
Allobarbitol	Chloroquine
Alphenal	α-Chlorpheniramine
Alprazolam (except BZ assay)	Chlorpromazine
Amitriptyline	Chloroamphetamine (DL-p-) Hydrochloride (except AM assay)
Amobarbital	Cholesterol
Amoxapine	Clobazam (except BZ assay)
Amoxicillin	Clozapine
d-Amphetamine (except AM assay)	Clonazepam (except BZ assay)
d,l-Amphetamine (except AM assay)	Cocaine (except CO assay)
l-Amphetamine (except AM assay)	Cocaine (except OP assay)
Ampicillin	Cortisone
Apomorphine	l-Coinine
Aprobarbital	Creatine
l-Ascorbic Acid	Creatinine
Aspartame	Cyclobenzaprine
Atropine	Delorazepam (except BZ assay)
Barbital	Deoxycortisone acetate
Benzilic acid	Desipramine (except ME/MDMA assay)
Benzocaine	Dextromethorphan
Benzoyllecgonine hydrate (except CO assay)	Diazepam (except BZ assay)
Benzoic acid	Dihydrocodeine (except OP assay)
Bilirubin	4-Dimethylaminoantipyrine
Bromazepam (except BZ assay)	Diphenhydramine
d-Brompheniramine	Dopamine
Buprenorphine	Doxepin hydrochloride

Doxylamine	Nitrazepam (except BZ assay)
Ecgonine (except CO assay)	11-Nor-Delta 8-THC-9-COOH (except TH assay)
Ecgonine Methyl Ester	11-Nor-Delta 9-THC-9-COOH (except TH assay)
l-Ephedrine	Nordiazepam (except BZ assay)
d,l-Ephedrine (except ME/MDMA assay)	Nordoxepin hydrochloride
1R, 2S l- Ephedrine (except ME/MDMA assay)	d,l-Norephedrine hydrochloride
1S, 2R d-Ephedrine	Norethindrone
l-Epinephrine	d-Norpropoxyphene
Erythromycin	Nortriptyline hydrochloride
Estazolam (except BZ assay)	Oxalic Acid
β-Estradiol	Oxazepam (except BZ assay)
Estrone-3-sulfate potassium salt	Oxolinic acid
Ethanol	Oxycodone
Ethylidene-1,5-Dimethyl-1-3,3- Diphenylpyrrolidine Perchlorate salt	Papaverine
Ethyl Morphine (except OP assay)	Penicillin-G (Benzylpenicillin)
Flunitrazepam (except BZ assay)	Pentazocine
Flurazepam (except BZ assay)	Pentobarbital
Furosemide	Perphenazine
Gentisic acid	Phencyclidine (except PC assay)
Glucose	Pheniramine
Glutethimide	Phenobarbital
Guaiacol Glyceryl Ether	Phenothiazine
Hemoglobin	Phentermine (except AM assay)
Heroin (except OP assay)	Phenylephrine (except ME/MDMA assay)
Hippuric acid	β-Phenylethylamine (except AM assay)
Hydrochlorothiazide	d,l-Phenylpropanolamine hydrochloride
Hydrocodone (except OP assay)	Prazepam (except BZ assay)
Hydrocortisone	Prednisolone
Hydromorphone (except OP assay)	Procaine
11-Hydroxy-D-9-Tetrahydrocannabinol (except TH assay)	Promazine
p-Hydroxymethamphetamine (Pholderin) (except ME/MDMA assay)	Promethazine
3-Hydroxytyramine	d-Propoxyphene
lbutrofen	Propritiyline
Imipramine	d-Pseudoephedrine HCl (except ME/MDMA assay)
d,l-isoproterenol	Quinidine
l-isoproterenol HCl	Ranitidine
Lidocaine	Riboflavin
Lorazepam (except BZ assay)	Salicylic acid
Lormetazepam (except BZ assay)	Secobarbital
MDMA (except ME/MDMA assay)	Serotonin
MDA (except AM assay)	Sodium Chloride
MDEA (except AM, ME/MDMA assays)	Sulfamethazine
Meperidine	Sulindac
d,l-Methadone	Temazepam (except BZ assay)
d-Methamphetamine (except ME/MDMA assay)	Tetracycline
d,l-Methamphetamine (except ME/MDMA assay)	Delta-8-Tetrahydrocannabinol (except TH assay)
l-Methamphetamine (except ME/MDMA assay)	Delta-9-Tetrahydrocannabinol (except TH assay)
Methaqualone	Thiamine
Methoxyphenamine (except ME/MDMA assay)	Thionidazine
2-Methylamine-Propiophenone HCl	Triazolam (except BZ assay)
Methylphenidate	Trifluoperazine
Morphine (except OP assay)	Trimethobenzamide (except ME/MDMA assay)
Morphine-3-beta -D-Glucuronide (except OP assay)	Trimipramine Maleate
Nalidixic acid	Tryptamine
Nalorphine (except OP assay)	d,l-Tryptophan
Naloxone	Tyramine (except AM assay)
Naltrexone hydrochloride	d,l-Tyrosine
d-Naproxen	Uric Acid
Niacinamide	Verapamil
	Zomepirac

Bibliography of Suggested Reading

1. Wong, R. The Current Status of Drug Testing in the US Workforce, American Clinical Laboratory, vol. 21(1), page 21-23, 2002.
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5. Wong, R. On-site Oral Fluid Drug Testing by Oratect, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H. ed., Humana Press, p146-158, 2005.

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