



Oratect® II Oral Fluid Drug Screen Device
MET/MDMA/THC/COC/AMP/OPI/PCP
 Catalog No. HM11

Intended Use

The Oratect® II 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 and their metabolites in human oral fluid. The Oratect® II Test detects these drugs at the following cut-off concentrations:

ME	d-Methamphetamine/MDMA	25 ng/ml
TH	Δ9-Tetrahydrocannabinol	40 ng/ml
CO	Cocaine	20 ng/ml
AM	d-Amphetamine	25 ng/ml
OP	Morphine	10 ng/ml
PC	Phencyclidine	4 ng/ml

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® II Oral Fluid Drug Screen Device provides only preliminary drug test results. For quantitative analytical results or for a confirmation of a presumptive positive result obtained by Oratect® II, 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® II was developed to detect active drugs-of-abuse present in saliva. Studies on methamphetamine, MDMA, cocaine, opiate, amphetamine, phencyclidine and cannabinoid show that all of these drugs are detectable in oral fluid. Oratect® II is designed to integrate oral fluid collection and a lateral flow immunoassay screening test for drugs-of-abuse in one single device.

Test Principle

The Oratect® II 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 colored 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 color band at the test region indicates a presumptive positive result for that particular test.

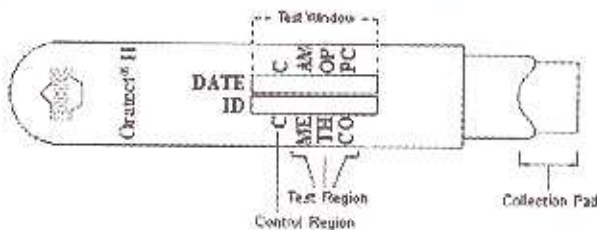


Fig. a Detail regions of Oratect® II

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® II test 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 test strip: Amphetamine, Morphine and Phencyclidine 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 test strip contains anti-amphetamine, anti-morphine and anti-phencyclidine antibody colloidal gold conjugates.

Collection Pad: The collection pad consists of an absorbent material

Materials Provided

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

- 1 Package Insert.
- 1 Reference Guide.
- 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.
- 1 plastic vial containing buffer for confirmation test.

Materials Required but Not Provided

- Timing device

Warnings and Precautions

- The Oratect® II 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 beyond 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® II 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 subject not to eat, drink, smoke or chew tobacco products.

Test Procedure

- Remove the test device from the sealed pouch.
- Carefully remove the blue cap by holding the sides and pull gently. This will expose the collection pad.
- The oral fluid collection process must be observed. Instruct the subject to hold the top portion of the device (above the test windows).
- When placing device into the mouth, keep head level
 - Open mouth and rub the collection pad inside mouth against one cheek gently in a circular motion twenty times. (Fig. b)
 - Still keeping head level, rub the collection pad against the opposite cheek in a circular motion twenty times. (Fig. b)

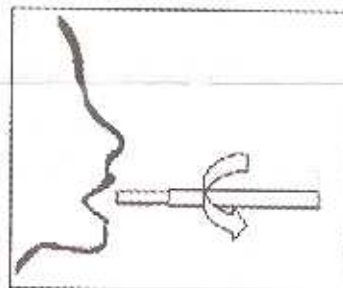


Fig. b Rub the collection pad against each cheek twenty times.

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

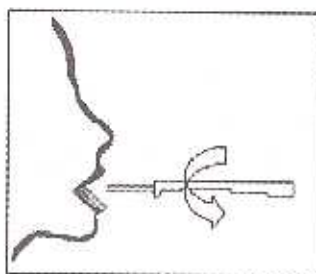


Fig. c Rub the collection pad on top of the tongue twenty times.

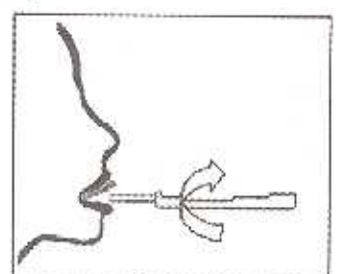


Fig. d Rub the collection pad underneath the tongue twenty times.

- Place the collection pad underneath the tongue to collect saliva. Instruct the donor to hold the device in place with their hand.
- If no pink-purple flow appears after 30 seconds, repeat the instructions in step 4 and 5 until the pink-purple flow appears.
- Remove the device from mouth as soon as pink-purple flow appears at both test windows.

Note: Pink-purple flow should appear in the test windows within 5 minutes. If no flow patterns are 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 7 minutes.

Interpreting Test Results

Negative Results

For each of the test windows, 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

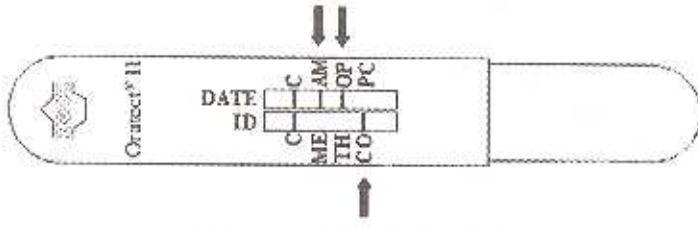


Fig. e. Example of Negative Test Results

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 Phenylephrine, Methamphetamine and THC because no bands are visible in the test regions of PC, ME, and TH.

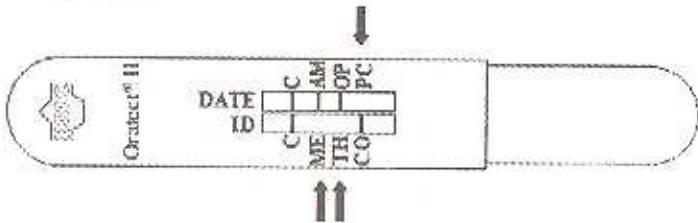


Fig. f. Example of Presumptive Positive Test Results

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, and samples. Repeat the test using a new device. In Fig. g below, the test is invalid because there are **no bands in the control regions**.

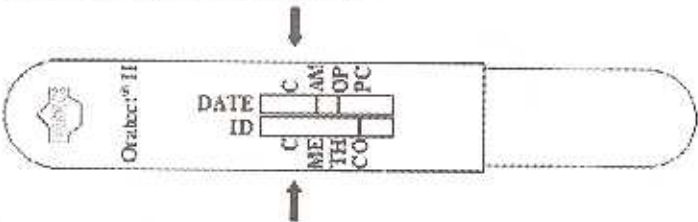


Fig. g. Example of Invalid Test Results

Important: Read each test independently. Do not compare color intensity of one test band to another. When a faint color band for a specific test is obtained in the test region, the sample should be considered negative. The Oratect II 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 (GC/MS or LC/MS) must be used.

Specimen Collection & Handling for Confirmation

- 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 II Oral Fluid Drug Screen Device provides built-in control bands at the control regions (C) to indicate that the test performed properly. These control bands should always appear regardless of the presence of drugs or metabolites. The presence of the colored bands in the control regions verifies that 1) adequate sample volumes have been used and 2) 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 drug/metabolite 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 II Drug Screen Tests are summarized below

Drug Test	Total # of Test/ Concentration	Concentration							
		0%		50%		200%		300%	
		-	+	-	+	-	+	-	+
MET	20	20	0	20	0	0	20	0	20
MDMA	20	20	0	20	0	0	20	0	20
THC	20	20	0	20	0	1	19	0	20
COC	20	20	0	20	0	0	20	0	20
AMP	20	20	0	20	0	0	20	0	20
OPI	20	20	0	20	0	0	20	0	20
PCP	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
MET/MDMA		
(-) Methamphetamine	25	100%
(+)-Methamphetamine	50	83%
MDMA	25	100%
MDEA	300	8.3%
p-Hydroxymethamphetamine	1000	2.5%
Methoxyphenamine	2500	1%
(+)-Ephedrine	5000	0.5%
Phenylephrine	7000	0.4%
Trimethobenzamide	4000	0.8%
AMP		
d-Amphetamine	25	100%
d,l-Amphetamine	40	62.5%
MDA	40	62.5%
MDEA	100	25%
dl-p-Chloramphetamine	200	12.5%
Phentermine	100	25%
Δ-Phenylethylamine	8000	0.3%
Tyramine	8000	0.3%
COC		
Cocaine	20	100%
Benzoylcegonine	18	110%
Egonine	5000	0.4%
OPI		
Morphine	10	100%
Codeine	10	100%
6-Acetylmorphine	12	83%
6-Acetylcodeine	20	50%
Morphine-3beta-D-glucuronide	25	40%
Ethylmorphine	60	17%
Heroin	15	67%
Hydromorphone	70	14%
Hydrocodone	60	17%
THC		
Delta 9-THC	40	100%
Delta 8-THC	100	40%
11-nor-Delta-8-THC-9-COOH	10	400%
11-hydroxy-Delta 9-THC	400	10%
Cannabinol	80	50%
Cannabidiol	>10,000	<0.4%
PCP		
Phencyclidine	4	100%

Interference

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

Acetaminophen	Dextromethorphan
Acetoacetic acid lithium salt	Diazepam
Acetone	Diclofenac Sodium Salt
Acetylsalicylic acid	4-Dimethylaminoantipyrine
6-Acetylcodine (except MOR assay)	Diphenhydramine
6-Acetylmorphine (except MOR assay)	Dopamine
Albumin	Doxopin hydrochloride
Alprazolam	Doxylamine
Amitriptyline	Ecgonine (except COC assay)
Amobarbital	Ecgonine Methyl Ester
Amoxapine	(-)-Ephedrine (1R, 2R-(-)-Pseudoephedrine)
Amoxicillin	(+)-Ephedrine (except MET assay)
d-Amphetamine (except AMP assay)	1R, 2S(-)- Ephedrine (except MET assay)
d,l-Amphetamine (except AMP assay)	1S, 2R(+)- Ephedrine
Ampicillin	(-)-Epinephrine
Alpha-Amylase	R-(-)-Epinephrine
Anhydroecgonine HCl	Erythromycin
Anhydroecgonine Methyl Ester	Estazolam
Apomorphine	Ethanol
L-Ascorbic Acid	Ethylidene-1,5-Dimethyl-1,3,3-Diphenylpyrrolidine Perchlorate salt
Aspartame	Ethynylestradiol 3-methyl ether (17alpha-)
Atropine	Ethyl Morphine (except MOR assay)
Benzocaine	2-Ethylidene-1,5-Dimethyl-1,3,3-Diphenyl
Benzoylcegonine hydrate (except COC assay)	Flunitrazepam
Bilirubin	Flurazepam
Bromazepam	Furosemide
(+) Brompheniramine	Genisic acid
Bupropion	GHB Sodium salt
Buprenorphine	Glucose
Buprenorphine Hydrochloride	Glucose-6-Phosphate Dehydrogenase
Butalbital	Glucose-6-Phosphate Disodium Salt Hydrate
Caffeine	Guaiacol Glyceryl Ether
Cannabinol (except THC assay)	Hemoglobin
Cannabidiol	Heroin (except MOR assay)
Chlordiazepoxide	Hippuric acid
Chloroquine	Hydrochlorothiazide
(+)Chlorpheniramine	Hydrocodone (except MOR assay)
Chlorpromazine	Hydromorphone (except MOR assay)
Chloramphenicol (DL-p-) Hydrochloride (except AMP assay)	11-Hydroxy-D-9-Tetrahydrocannabinol (except THC assay)
Clabazam	11-Hydroxy-D-9-Tetrahydrocannabinol-9-Carboxylic Acid (except THC assay)
Clomipramine	5-Hydroxyindole-3-Acetic acid (5-HIAA)
Clonazepam	p-Hydroxymethamphetamine (Pholderin) (except MET assay)
Clorazepate	Hydroxytyramine
Cocaine (except COC assay)	Ibuprofen
Codeine (except MOR assay)	Imipramine
(-)Cotinine	Ketamine HCl
Creatine	L-Lactic Dehydrogenase
Creatinine	Lidocaine
Cyclobenzaprine	Lorazepam
Delorazepam	Lormetazepam
Desipramine	(+)-MDMA (except AMP, MET assays)
Desmethyldiazepam	(+)-MDA (except AMP assay)
Dextran	(+)-MDEA (except AMP, MET assays)
	Maperidine
	(-)-Mefenadone
	(+)-Methamphetamine (except MET assay)
	(+)-Methamphetamine (except MET assay)
	Methaqualone

Methoxyphenamine (except MET assay)
2-Methylamine-Propiophenone HCl
Methylphenidate
Morphine (except MOR assay)
Morphine-3-beta -D-Glucuronide (except MOR assay)
Nalidixic acid
Naloxone
(+)-Naproxen
Niacinamide
S(-)-Nicotine
Nicotinic Acid
Nitrazepam
(-)-11-Nor-9-Carboxy-Delta9-THC (except THC assay)
Nordoxepin hydrochloride
d,l-Norephedrine hydrochloride
Norethindrone
d-Norpropoxyphene
Nortriptyline hydrochloride
Oxalic Acid
Oxazepam
Oxolinic acid
Oxycodone (except MOR assay)
Papaverine
Penicillin-G (Benzylpenicillin)
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine (except PCP assay)
Pheniramine
Phenobarbital
Phenothiazine
Phentermine (except AMP assay)
Phenylephrine (except MET assay)
β-Phenylethylamine (except AMP assay)
(+/-)-Phenylpropanolamine hydrochloride
Prazepam
Procaine
Promazine
Promethazine
d-Propoxyphene
Protriptyline
d-Pseudoephedrine HCl
Quinidine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital
Serotonin
Sodium Chloride
Sodium Tartrate
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Delta-8-Tetrahydrocannabinol (except THC assay)
Delta-9-Tetrahydrocannabinol (except THC assay)

Thiamine
Thiondazine
Thiaminolone
Triazolam
Trifluoperazine
Trimethobenzamide (except MET assay)
Trimipramine Malcate
Trypsin-chymotrypsin Inhibitor
Tryptamine
d,l-Tryptophan
Tyramine (except AMP assay)
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

Bibliography of Suggested Reading

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3. Schramm, W., Smith, R. and Craig, P., Drugs of Abuse in Saliva: A Review, J. Analytical Toxicology, vol. 18, p. 1-9, 1992.
4. Mandatory Guidelines for Federal Workplace Drug Testing Programs, April 13, 2004 (69 FR 19644).
5. Wong, R. On-site Oral Fluid Drug Testing by Orafect, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H ed., Humana Press, p146-150, 2005.

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