



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.

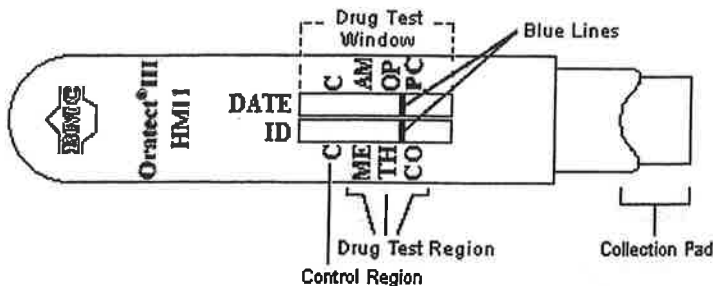


Fig. a Detail regions of Oratect® III Oral Fluid Drug Screen Device

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 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® 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)

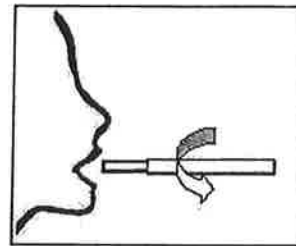


Fig. b Gently rub the collection pad against each cheek several (approximately 15-20) times.

- 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.

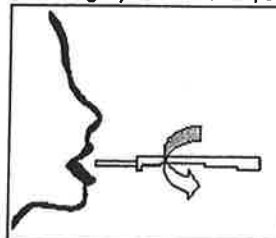


Fig. c Gently rub the collection pad on top of the tongue several (approximately 15-20) times.

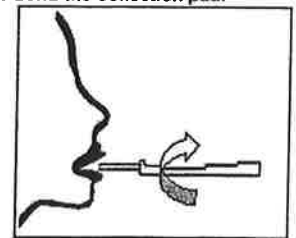


Fig. d Gently rub the collection pad underneath the tongue several (approximately 15-20) times.

- 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.

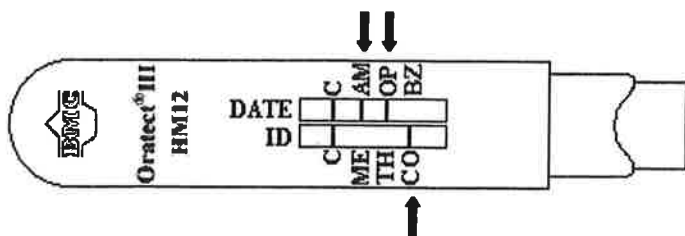


Fig. e. Example of Negative Test Results

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.

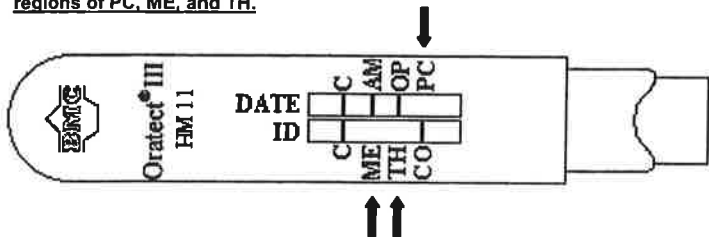


Fig. f. Example of Presumptive Positive Test Results

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.

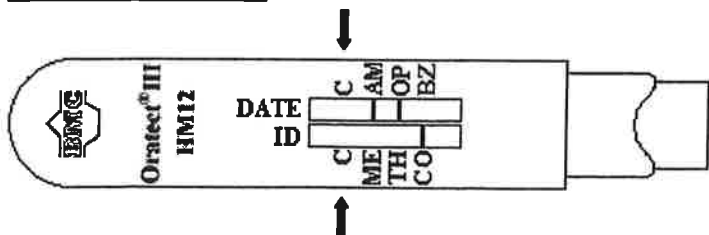


Fig. g. Example of Invalid Test Results

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 Oratec[®] 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 Oratec[®] III Oral Fluid Drug Screen Device provides two built-in control bands at the control regions (C) to indicate that the test has been 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 Oratec[®] III Oral Fluid Drug Screen Device Tests are

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

summarized below:

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		
Benzoylcegonine	18	110%
Cocaine	20	100%
Ecgonine	5000	0.4%

Drug Test	Approximate Concentration (ng/ml)	Approximate % Cross Reactivity	Doxylamine	Nitrazepam (except BZ assay)
AM			Ecgonine (except CO assay)	11-Nor-Delta 8-THC-9-COOH (except TH assay)
d-Amphetamine	25	100%	Ecgonine Methyl Ester	11-Nor-Delta 9-THC-9-COOH (except TH assay)
d,l-Amphetamine	40	62.5%	l-Ephedrine	Nordiazepam (except BZ assay)
l-Amphetamine	800	3.2%	d,l-Ephedrine (except ME/MDMA assay)	Nordoxepin hydrochloride
d,l-p-Chloramphetamine	200	12.5%	1R, 2S l-Ephedrine (except ME/MDMA assay)	d,l-Norephedrine hydrochloride
MDA	40	62.5%	1S, 2R d-Ephedrine	Norethindrone
MDEA	100	25%	l-Epinephrine	d-Norpropoxyphene
Phentermine	100	25%	Erythromycin	Nortriptyline hydrochloride
β-Phenylethylamine	8000	0.3%	Estazolam (except BZ assay)	Oxalic Acid
Tyramine	8000	0.3%	β-Estradiol	Oxazepam (except BZ assay)
OP			Estrone-3-sulfate potassium salt	Oxolinic acid
6-Acetylcodeine	20	50%	Ethanol	Oxycodone
6-Acetylmorphine	12	83%	Ethylidene-1,5-Dimethyl-1,3,3-Diphenylpyrrolidine Perchlorate salt	Papaverine
Codeine	10	100%	Ethyl Morphine (except OP assay)	Penicillin-G (Benzylpenicillin)
Dihydrocodeine	10	100%	Flunitrazepam (except BZ assay)	Pentazocine
Ethyl morphine	60	17%	Flurazepam (except BZ assay)	Pentobarbital
Heroin	15	67%	Furosemide	Perphenazine
Hydrocodone	60	17%	Gentisic acid	Phencyclidine (except PC assay)
Hydromorphone	70	14%	Glucose	Pheniramine
Morphine	10	100%	Glutethimide	Phenobarbital
Morphine-3-beta-D-Glucuronide	25	40%	Guaiacol Glyceryl Ether	Phenothiazine
Nalorphine	100	10%	Hemoglobin	Phentermine (except AM assay)
PC			Heroin (except OP assay)	Phenylephrine (except ME/MDMA assay)
Phencyclidine	4	100%	Hippuric acid	β-Phenylethylamine (except AM assay)
BZ			Hydrochlorothiazide	d,l-Phenylpropanolamine hydrochloride
Alprazolam	4	125%	Hydrocodone (except OP assay)	Prazepam (except BZ assay)
Bromazepam	4	125%	Hydrocortisone	Prednisolone
Chlordiazepoxide	50	10%	Hydromorphone (except OP assay)	Procaine
Clobazam	10	50%	11-Hydroxy-D-9-Tetrahydrocannabinol (except TH assay)	Promazine
Clonazepam	20	25%	p-Hydroxymethamphetamine (Pholderin) (except ME/MDMA assay)	Promethazine
Delorazepam	5	100%	3-Hydroxytyramine	d-Propoxyphene
Diazepam	5	100%	Ibuprofen	Protriptyline
Estazolam	3	167%	Imipramine	d-Pseudoephedrine HCl (except ME/MDMA assay)
Flunitrazepam	8	63%	d,l-Isoproterenol	Quinidine
Flurazepam	10	50%	l-Isoproterenol HCl	Ranitidine
Lorazepam	10	50%	Lidocaine	Riboflavin
Lometazepam	15	33%	Lorazepam (except BZ assay)	Salicylic acid
Nitrazepam	4	25%	Lormetazepam (except BZ assay)	Secobarbital
Nordiazepam	3	67%	MDMA (except ME/MDMA assay)	Serotonin
Oxazepam	5	100%	MDA (except AM assay)	Sodium Chloride
Prazepam	10	50%	MDEA (except AM, ME/MDMA assays)	Sulfamethazine
Temazepam	5	100%	Meperidine	Sulindac
Triazolam	10	50%	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)	Thioridazine
			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

Interference

The following compounds were spiked into artificial oral fluid solution and found not to cross-react with the Oratec® 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-Acetylcodeine (except OP assay)	Cannabidiol
6-Acetylmorphine (except OP assay)	Chloral Hydrate
Albumin	Chlordiazepoxide (except BZ assay)
Allobarbitol	Chloroquine
Alphenal	d-Chlorpheniramine
Alprazolam (except BZ assay)	Chlorpromazine
Amitriptyline	Chloroamphetamine (DL-p)-Hydrochloride (except AM assay)
Amobarbital	Cholesterol
Amoxapine	Clobazam (except BZ assay)
Amoxicillin	Clomipramine
d-Amphetamine (except AM assay)	Clonazepam (except BZ assay)
d,l-Amphetamine (except AM assay)	Cocaine (except CO assay)
l-Amphetamine (except AM assay)	Codeine (except OP assay)
Ampicillin	Cortisone
Apomorphine	l-Cotinine
Aprobarbital	Creatine
l-Ascorbic Acid	Creatinine
Aspartame	Cyclobenzaprine
Atropine	Delorazepam (except BZ assay)
Barbital	Deoxycortisone acetate
Benzillic 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

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.
2. Caplan, Y. and Goldberger, B., Alternative Specimens for Workplace Drug Testing, J. Analytical Toxicology, vol. 25, p. 396-399, 2001.
3. Schramm, W., Smith, R. and Craig, P., Drugs of Abuse in Saliva: A Review, J. Analytical Toxicology, vol. 16, 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 Oratec, in Drugs of Abuse: Body Fluid Testing, Wong, R and Tse, H ed., Humana Press, p146-158, 2005.

Manufactured By:
 Branan Medical Corporation
 Irvine, CA 92618
 USA
 1-866-468-3287 (1-866-INTECT7) Domestic U.S. & Canada
 1-949-598-7166 International
 Part No.: PI-HM, Rev: C, 03/07



Oratect® III Reference Guide

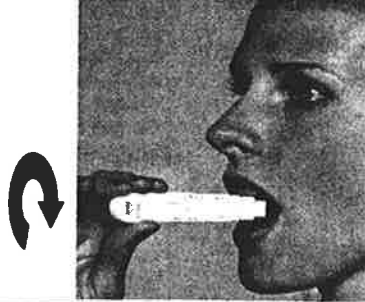
The Oratect® III* Oral Fluid Drug Screen Device is a simple one-step test for the detection of drugs of abuse in oral fluid.

Oratect® III Procedures -- Refer to package insert for detailed instructions and technical information.

1. Remove the blue cap by holding the sides and pulling gently. This will expose the collection pad. Make sure there is a blue line present in each window area indicating an unused device.



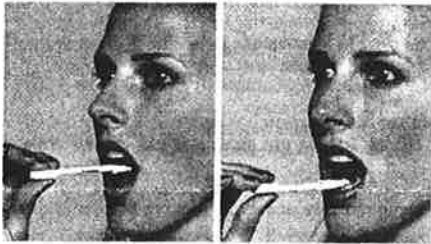
2. Open mouth and gently rub the collection pad inside mouth against cheek in a circular motion several (approximately 15-20) times. Make sure to keep head level.



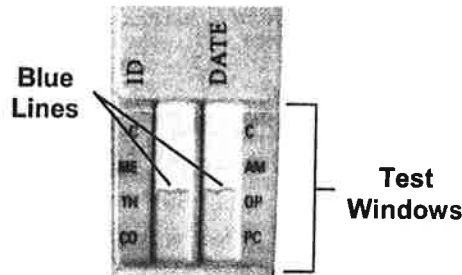
3. Gently rub the collection pad against the opposite cheek in circular motion several (approximately 15-20) times.



4. Gently rub the collection pad on top of the tongue several (approximately 15-20) times. Do not chew, suck, bite or bend the collection pad.



6. Place the collection pad underneath the tongue for approximately 30 seconds to collect saliva. Instruct the donor to hold the device in place with hand. Sufficient amount of saliva collected is indicated by the flow of the blue lines. Repeat steps 2-6 until blue lines flow.



7. Remove from mouth as soon as blue lines flow at both of the test windows. Re-cap the device.



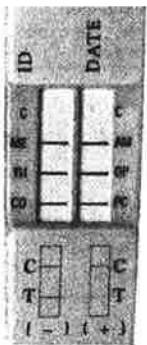
5. Rub the collection pad underneath the tongue several (approximately 15-20) times.

8. Lay the device on a flat surface and read results in 5 minutes after removing the device from mouth. Do not read results after 30 minutes.

Interpreting Oratect® III Test Results

Invalid Result

When no colored band appears in the CONTROL (C) region, the test is invalid even if there is a band in the test region. Repeat the test with a new device.



Example Interpretation:

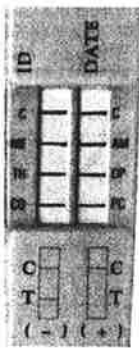
ME: Invalid
TH: Invalid
CO: Invalid
AM: Invalid
OP: Invalid
PC: Invalid

Negative Result

For each test, two colored bands should be observed:

- One in the CONTROL (C) region
- One in the specific TEST region

The color of the test band may be slightly darker or lighter than the control band. Any visible band that can be seen is a negative result.



Example Interpretation:

ME: Negative
TH: Negative
CO: Negative
AM: Negative
OP: Negative
PC: Negative

Presumptive Positive Result

A colored band at the CONTROL (C) region should be observed. When there is no colored band at the specific TEST region, the test is presumptive positive for that particular drug.



Example Interpretation:

ME: Presumptive Positive
TH: Negative
CO: Negative
AM: Negative
OP: Negative
PC: Negative