Branan Medical Corporation

OratectPlus™ Oral Fluid Drug and Alcohol Screen Device

ME/TH/CO/AM/OP/PC or BZ and Alcohol

Catalog No. HMA11 & HMA12

Intended Use

The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device is designed for the qualitative detection of drugs of abuse and alcohol simultaneously in human saliva. It 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. In addition, it is an one step enzymatic color test for the qualitative detection of alcohol in human oral fluid. The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device detects these drugs and alcohol 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
BZ	Diazepam	5 ng/ml
AL	Alcohol	≥ 0.02 % B.A.C

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/alcohol test results. For quantitative results or for a confirmation of a presumptive positive result obtained by OratectPlus™ Oral Fluid Drug and Alcohol Screen Device, a more specific alternative method must be used.

Summary and Explanation

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

Studies on methamphetamine, MDMA, cocaine, opiate, amphetamine, phencyclidine, benzodiazepine, cannabinoid and alcohol show that all of them are detectable in oral fluid. OratectPlus™ Oral Fluid Drug and Alcohol Screen Device is designed to integrate oral fluid collection and simultaneous testing for drugs-of-abuse and alcohol in one single device.

Test Principle

The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device is based on :

(1) Drug tests: A competitive lateral flow immunoassay 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 is 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.**

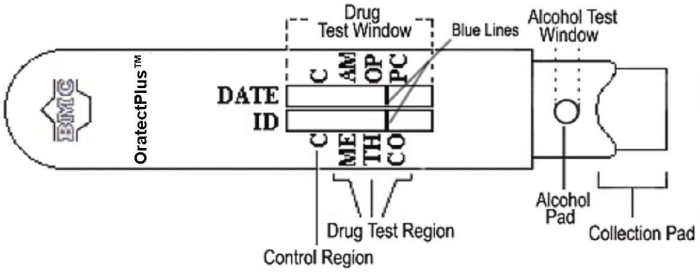

Fig. A Detailed regions of OratectPlus™ Oral Fluid Drug and Alcohol Screen Device

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.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} \underset{}{H}CH_3C{=}O + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} \underset{\text{Blue}}{D} + 2H_2O$$

During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (remains white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidaze to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive positive result for alcohol.

Reagents

The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device contains:

(1) Drug Tests: The drug tests consist of 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 regions on the membrane known as the "Test Region".

AM/OP/PC or AM/OP/BZ test strip: Amphetamine, Morphine and Phencyclidine or Amphetamine, Morphine and 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 and anti-phencyclidine or anti-amphetamine, anti-morphine and anti-benzodiazepine antibody colloidal gold conjugates.

(2) Alcohol Test: The alcohol pad contains

Tetramethylbenzidine,
Alcohol Oxidaze,
Peroxidase,
Buffer and
Stabilizing Proteins

Materials Provided

Each OratectPlus™ Oral Fluid Drug and Alcohol 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 an oxygen absorber-dessicant.
4. 1 plastic vial, containing buffer for confirmation test.

Materials Required but Not Provided

- Timing device

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 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.
- Persons who are color blind or visually impaired should not interpret test results.

The alcohol test is designed and calibrated to be interpreted 5 minutes after starting the saliva collection procedure. Waiting longer than 10 minutes may result in erroneous results or false positive results. The alcohol test is highly sensitive to the presence of alcohol. The alcohol vapors in air are sometimes detected by the OratectPlus™ Oral Fluid Drug and Alcohol Screen Device. Alcohol vapors are often present in many institutions and homes. Alcohol is a component in many household products such as disinfectants, deodorizers, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of these vapors.

The alcohol test is a visually interpreted test where any color change to green or blue is considered a presumptive positive result with the alcohol concentration of 0.02% Blood Alcohol Concentration or higher in the saliva.

Product Storage

The OratectPlus™ Oral Fluid Drug and Alcohol Screen Device pouch should be stored at room temperature, 15°-30°C (59°F-86°F) and **not to exceed 30°C (86°F).** Under this condition, the alcohol test will perform according to specification until the expiration date.

If storage temperature exceeds 30°C (86°F), degradation of the product and performance may occur.

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 gum or tobacco products because it can provide erroneous results due to possible contamination of the saliva by interfering substances.

Test Procedure

1. Remove the test device from the sealed pouch.
2. Carefully remove the clear cap by holding the sides and pull gently. This will expose the collection pad and a round alcohol pad beneath the alcohol window.
3. Ensure that the blue line is 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, the 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 test windows).
6. 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, rub the collection pad against the opposite cheek in a circular motion several (approximately 15-20) times. **(Fig. B)**

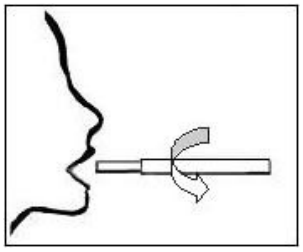

Fig. B Rub the collection pad against each cheek several (approximately 15-20) times.

   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.**

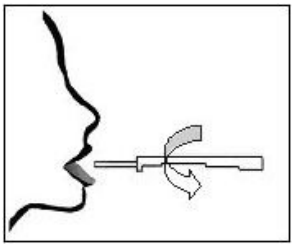

Fig. C Rub the collection pad on top of the tongue several (approximately 15-20) times.

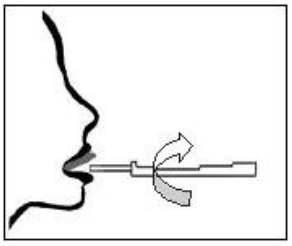

Fig. D Rub the collection pad underneath the tongue several (approximately 15-20) times.

7. 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.
8. 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 7 until the blue lines flow.

   Note: The flow of the blue lines 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.
9. Re-cap the device, lay it on a flat surface and read results**:**
   (a) Alcohol test should be read at 5 minutes after removing device from the mouth. Do not read results after 10 minutes.
   (b) Drug tests should be read at 5 minutes after removing device from mouth. Do not read results after 30 minutes.

Interpreting Test Results

(1) Alcohol Test Results

(A) Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream colored); it should be interpreted as a negative result (no alcohol present). See Fig. E for an example of alcohol Negative Test result.

The **Fig. E** below, the oral fluid sample is negative for Alcohol **because there is no color change from the alcohol pad**.

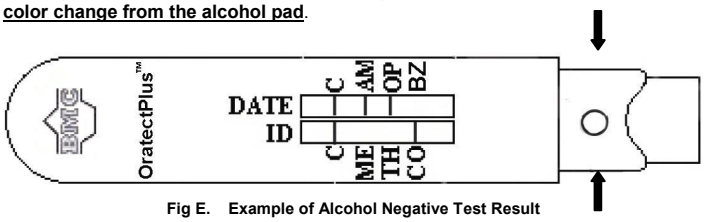

Fig E. Example of Alcohol Negative Test Result

A result where the outer edges of the alcohol pad produces 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. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

(B) Alcohol Presumptive Positive Result: The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02 % B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

The **Fig. F** below, the oral fluid sample is positive for Alcohol **because there is a color change (green / blue to dark gray) from the alcohol pad**.

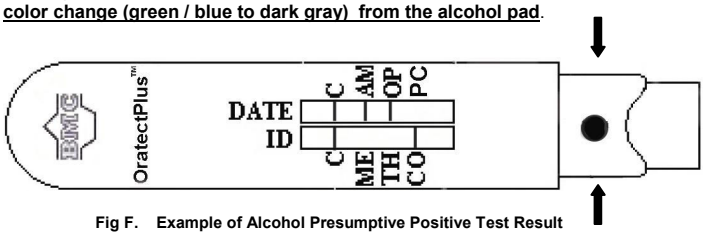

Fig F. Example of Alcohol Presumptive Positive Test Result

(2) Drug Test Results

(A) Drug Negative Results: For each of the drug 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 G.

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

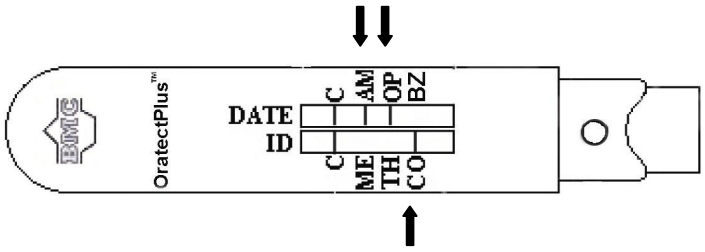

Fig. G Example of Drug Negative Test Results

(B) Drug 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. H below, the oral fluid sample is presumptive positive for Phencyclidine, Methamphetamine and THC because no bands are visible in the test regions of PC, ME, and TH.

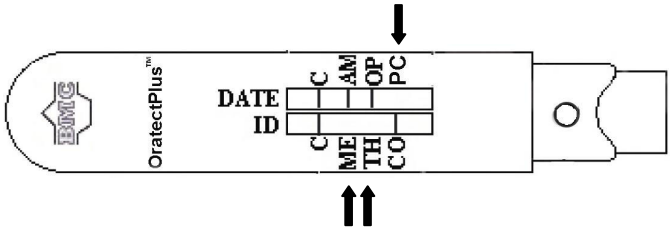

Fig. H Example of Drug Presumptive Positive Test Results

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

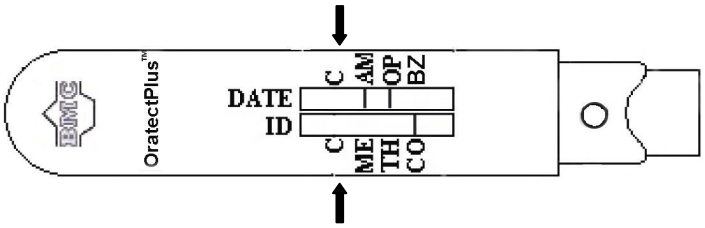

Fig. I Example of Invalid Test Results

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 OratectPlus™ Oral Fluid Drug and Alcohol Screen Device provides qualitative results for the presence of drug(s) and alcohol at specified cut-off concentration(s). For confirmation of a presumptive positive drugs-of-abuse result, a more specific quantitative method (GC/MS or LC/MS) must be used.

Specimen Collection & Handling for Confirmation Testing

- For devices with any presumptive positive results, the collection pad should be removed and sent for confirmation test.
- Squeeze the clear cap over the collection pad and detach both the clear cap and the collection pad. 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 as soon as possible from collection).
- Follow standard chain of custody procedures.
- To confirm presumptive positive alcohol test results a breathalyzer or blood test should be used.

Quality Control

The OratectPlus™ Oral Fluid Drug and Alcohol 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. 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 drugs and /or alcohol. However, it does 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 – Drugs-of-Abuse Tests

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 OratectPlus™ Oral Fluid Drug and Alcohol Screen Device 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
BZ	20	20	0	20	0	0	20	0	20

Precision – Alcohol Test

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.02%, 0.04% and 0.06%). Negative saliva was used to test at 0% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the OratectPlus™ Oral Fluid Drug and Alcohol Screen Device are summarized below:

Test	Total # of Test/ Concentration	B.A.C.							
		0.00%		0.02%		0.04%		0.06%	
		-	+	-	+	-	+	-	+
Alcohol	15	15	0	1	14	0	15	0	15

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-Δ9-THC	400	10%
CO		
Benzoylecgonine	18	110%
Cocaine	20	100%
Ecgonine	5000	0.4%
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-Acetylcodeine	20	50%
6-Acetylmorphine	12	83%
Codeine	10	100%
Dihydrocodeine	10	100%
Ethyl morphine	60	17%
Heroin	15	67%
Hydrocodone	60	17%
Hydromophone	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%

Alcohol Test

The Alcohol test will react with methyl, ethyl,and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

Interference

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

Acetaminophen
Acetoacetic acid lithium salt
Acetone
6-Acetylcodeine *(except OP assay)*
6-Acetylmorphine *(except OP assay)*
Acetylsalicylic acid
Albumin
Allobarbital
Alphenal
Alprazolam *(except BZ assay)*
Amitriptyline
Amobarbital
Amoxapine
Amoxicillin
d-Amphetamine *(except AM assay)*
d,l-Amphetamine *(except AM assay)*
l-Amphetamine *(except AM assay)*
Ampicillin
Apomorphine
Aprobarbital
l-Ascorbic Acid
Aspartame
Atropine
Barbital
Benzillic acid
Benzocaine
Benzoic acid
Benzoylecgonine hydrate *(except CO assay)*
Bilirubin
Bromazepam *(except BZ assay)*
d-Brompheniramine
BuprenorphineButalbital
Butethal
Caffeine
Cannabidiol
Cannabinol *(except TH assay)*
Chloral Hydrate
Chlordiazepoxide *(except BZ assay)*
Chloroamphetamine (DL-p-) Hydrochloride *(except AM assay)*
Chloroquine
d-Chlorpheniramine
Chlorpromazine
Cholesterol
Clobazam *(except BZ assay)*
Clomipramine
Clonazepam *(except BZ assay)*
Cocaine *(except CO assay)*
Codeine *(except OP assay)*
Cortisone
l-Cotinine
Creatine
Creatinine
Cyclobenzaprine
Delorazepam *(except BZ assay)*
Deoxycortisone acetate
Desipramine *(except ME assay)*
Dextromethorphan
Diazepam *(except BZ assay)*
Dihydrocodeine *(except OP assay)*
4-Dimethylaminoantipyrine
Diphenhydramine
Dopamine
Doxepin hydrochloride
Doxylamine
Ecgonine *(except CO assay)*
Ecgonine Methyl Ester
d,l-Ephedrine *(except ME assay)*
l-Ephedrine
1R, 2S l- Ephedrine *(except ME assay)*
1S, 2R d-Ephedrine
l-Epinephrine
Erythromycin
Estazolam *(except BZ assay)*
β-Estradiol
Estrone-3-sulfate potassium salt
Ethanol
Ethylidene-1,5-Dimethyl-1-3,3-Diphenylpyrrolindine Perchlorate salt
Ethyl Morphine *(except OP assay)*
Flunitrazepam *(except BZ assay)*
Flurazepam *(except BZ assay)*
Furosemide
Gentisic acid
Glucose
Glutethimide
Guaiacol Glyceryl Ether
Hemoglobin
Heroin *(except OP assay)*
Hippuric acid
Hydrochlorothizide
Hydrocodone *(except OP assay)*
Hydrocortisone
Hydromorphone *(except OP assay)*
11- Hydroxy-Δ-9-Tetrahydrocannabinol *(except TH assay)*
p-Hydroxymethamphetamine (Pholderin) *(except ME assay)*
3-Hydroxytyramine
Ibuprofen
Imipramine
d,l-Isoproterenol
l-Isoproterenol HCl
Lidocaine
Lorazepam *(except BZ assay)*
Lormetazepam *(except BZ assay)*
Meperidine
d,l-Methadone
d-Methamphetamine *(except ME assay)*
d,l-Methamphetamine *(except ME assay)*
l-Methamphetamine *(except ME assay)*
Methaqualone
Methoxyphenamine *(except ME assay)*
2-Methylamine-Propiophenone HCl
MDA *(except AM assay)*
MDEA *(except AM, ME assays)*
MDMA *(except ME assay)*
Methylphenidate
Morphine (*except OP assay)*
Morphine-3-beta -D-Glucuronide *(except OP assay)*
Nalidixic acid
Nalorphine *(except OP assay)*
Naloxone
Naltrexone hydrochloride
d-Naproxen
Niacinamide
Nitrazepam *(except BZ assay)*
11-Nor-Delta 8-THC-9-COOH *(except TH assay)*
11-Nor-Delta 9-THC-9-COOH *(except TH assay)*
Nordiazepam *(except BZ assay)*
Nordoxepin hydrochloride
d,l-Norephedrine hydrochloride
Norethindrone
d-Norpropoxyphene
Nortriptyline hydrochloride
Oxalic Acid
Oxazepam *(except BZ assay)*
Oxolinic acid
Oxycodone
Papaverine
Penicillin-G (Benzylpenicillin)
Pentazocine
Pentobarbital
Perphenazine
Phencyclidine *(except PC assay)*
Pheniramine
Phenobarbital
Phenothiazine
Phentermine *(except AM assay)*
Phenylephrine *(except ME assay)*
β-Phenylethylamine *(except AM assay)*
d,l-Phenylpropanolamine hydrochloride
Prazepam *(except BZ assay)*
Prednisolone
Procaine
Promazine
Promethazine
d-Propoxyphene
Protriptyline
d-Pseudoephedrine HCl *(except ME assay)*
Quinidine
Ranitidine
Riboflavin
Salicylic acid
Secobarbital
Serotonin
Sodium Chloride
Sulfamethazine
Sulindac
Temazepam *(except BZ assay)*
Tetracycline
Δ-8-Tetrahydrocannabinol *(except TH assay)*
Δ-9-Tetrahydrocannabinol *(except TH assay)*
Thiamine
Thioridazine
Triazolam *(except BZ assay)*
Trifluoperazine
Trimethobenzamide *(except ME assay)*
Trimipramine Maleate
Tryptamine
d,l-Tryptophan
Tyramine *(except AM assay)*
d,l-Tyrosine
Uric Acid
Verapamil
Zomepirac

Alcohol Test

The following substances may interfere with the OratectPlus™ Oral Fluid Drug and Alcohol Screen Device when using samples other than oral fluid:

(1) Agents which enhance color development: Peroxides and strong oxidizers

(2) Agents which inhibit color development:
Reducing Agents: Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, and Uric acid.
Bilirubin, L-dopa, L-methyldopa, and Methampyrone

The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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