

PRODUCT INFORMATION

DIPRO
Salive₅
Oral Fluid Drug Screen Device
COC, MDMA, AMP, THC, OPI

REF PM18 25 tests

IVD For in vitro Diagnostic Use

GB

Intended Use

The Dipro Salive 5 Oral Fluid Drug Screen Device is a one-step lateral flow immunoassay device for the qualitative detection of cocaine, methylenedioxymethamphetamine, amphetamine, THC, and morphine in human oral fluid. The Dipro Salive 5 Test detects these drugs at the following cut-off concentrations:

COC	Cocaine	20 ng/ml
MDMA	3,4-Methylenedioxymethamphetamine	50 ng/ml
AMP	d-Amphetamine	50 ng/ml
THC	Delta-9-Tetrahydrocannabinol	25 ng/ml
OPI	Morphine	10 ng/ml

The test is intended to be administered by a trained professional. It should not be used without supervision. This product is an in vitro diagnostic medical device intended for forensic use.

The Dipro Salive 5 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 Dipro Salive 5 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.

Dipro Salive 5 Oral Fluid Drug Screen Device is developed to detect active drugs-of-abuse present in saliva. Studies on cocaine, MDMA, amphetamine, cannabinoids and opiate show that all of these drugs are detectable in oral fluids. Dipro Salive 5 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 Dipro Salive 5 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 coloured 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 coloured 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 coloured colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the coloured 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.

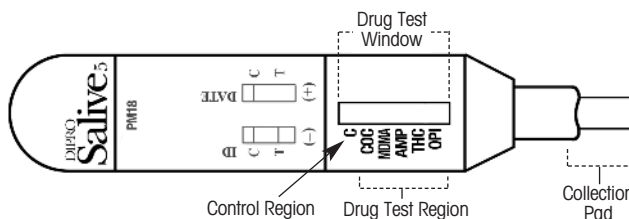


Fig. a: Dipro Salive 5 Oral Fluid Drug Screen Device

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 Dipro Salive 5 Oral Fluid Drug Screen Device contains a membrane strip and a collection pad. The strip consists of a membrane, a colloidal gold conjugate pad, a sample pad and an absorbent pad.

Membrane: Cocaine, MDMA, Amphetamine, THC and Opiate-protein conjugates are coated onto specific region on the membrane known as the Test Region.

Colloidal Gold Conjugate Pad: The colloidal gold conjugate pad for the test strip contains anti-cocaine, anti-MDMA, anti-amphetamine, anti-THC and anti-morphine antibody colloidal gold conjugates coated onto a fibrous pad.

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

Materials Provided

Each Dipro Salive 5 Oral Fluid Drug Screen Device kit contains:

- 1 Product Information.
- 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 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 Dipro Salive 5 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. The oral fluid collection process must be observed. Instruct the donor to hold the top portion of the device (above the test window).
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)

- a) Still keeping head level, gently rub the collection pad against the opposite cheek in a circular motion (approximately 15–20) several times. (Fig. b)

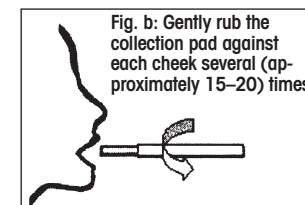


Fig. b: Gently rub the collection pad against each cheek several (approximately 15–20) times.

- 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.

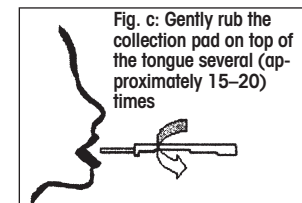


Fig. c: Gently rub the collection pad on top of the tongue several (approximately 15–20) times

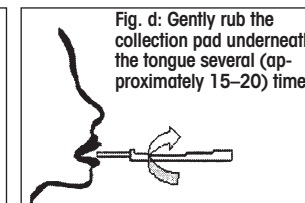


Fig. d: Gently rub the collection pad underneath the tongue several (approximately 15–20) times

5. 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.
6. The flow of the purple-red liquid indicates the collection of a sufficient amount of saliva. If the flow of the purple-red liquid is not observed after placing the collection pad underneath the tongue for 30 seconds, repeat the instructions in step 5 and 6 until the purple-red liquid flows.
7. Remove the device from mouth once the purple-red liquid starts to move at the test window.

Note: The flow of the purple-red liquid should appear in the test window within 4 minutes. If no flow is observed after 4 minutes in the mouth, discard the device, review procedures 4–7 above with the donor and repeat the test using a new device.
8. 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 test, purple-red colored bands should be observed; one band at the control region (C) and one band at the specific drug abbreviation (e.g. COC, MDMA, AMP, THC, OPI) 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.



Fig. e: Example of Negative Test Results (THC, OPI)

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 MDMA and cocaine (COC) **because no bands are visible in the test regions of MDMA and COC.**

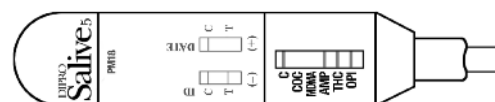


Fig. f: Example of Presumptive Positive Test Results (COC, MDMA)

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 is **no band in the control region**.

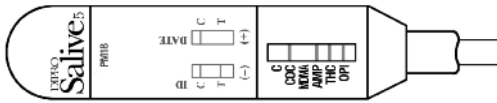


Fig. g: Example of Invalid Test Results (no C-band)

Important: Read each test independently. Do not compare colour 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 Dipro Salive 5 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 Dipro Salive 5 Oral Fluid Drug Screen Device provides a built-in control band at the control region (C) to indicate that the test has performed properly. The control band should always appear regardless of the presence of drugs. The presence of the purple-red band in the control region verifies that proper flow was obtained. If the control band does 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 Dipro Salive 5 Oral Fluid Drug Screen Device Tests are summarized below:

Drug Test	Total # of Test/ Concentration	Concentration							
		0%		50%		200%		300%	
		-	+	-	+	-	+	-	+
COC	20	20	0	20	0	20	0	20	0
MDMA	20	20	0	20	0	20	0	20	0
AMP	20	20	0	20	0	20	0	20	0
THC	20	20	0	20	0	20	0	20	0
OPI	20	20	0	20	0	20	0	20	0

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
COC		
Benzoylcegonine	100	20%
Cocaine	20	100%
Ecgonine	5000	0.4%
Ecgonine Methyl Ester	10000	0.2%
MDMA		
MDA	500	10%
MDEA	25	200%
MDMA	50	100%
d-Methamphetamine	10000	0.5%
AMP		
d-Amphetamine	50	100%
d,l-Amphetamine	80	62.5%
l-Amphetamine	1000	5%
d,l-p-Chloramphetamine	100	50%
MDA	80	62.5%
MDEA	10000	0.5%
Phentermine	125	40%
β-Phenylethylamine	3000	16.6%
Tryptamine	7500	0.7%
Tyramine	7500	0.7%
THC		
Cannabinol	50	50%
Δ-8-Tetrahydrocannabinol	62	40%
Δ-9-Tetrahydrocannabinol	25	100%
11-nor-Δ-8-THC-9-COOH	6	400%
11-nor-Δ-9-THC-9-COOH	6	400%
11-Hydroxy-Δ-9-THC	250	10%
OPI		
6-Acetylcodeine	20	50%
6-Acetylmorphine	10	83%
Codeine	10	100%
Dihydrocodeine	10	100%
Ecgonine Methyl Ester	10000	0.1%
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%

Interference

The following compounds were spiked into artificial oral fluid solution and found not to cross-react with the Dipro Salive 5 Oral Fluid Drug Screen Device when tested at concentration of 10 µg/ml (10,000 ng/ml).

Acetaminophen	Atropine	Clomipramine
Acetoacetic acid lithium salt	Barbital	Clonazepam
Acetone	Benzilic acid	Cocaine (except COC assay)
Acetylsalicylic acid	Benzocaine	Codeine (except OPI assay)
6-Acetylcodeine	Benzoylcegonine hydrate	Cortisone
(except OPI assay)	(except COC assay)	l-Colinine
6-Acetylmorphine	Benzoic acid	Creatine
(except OPI assay)	Bilirubin	Creatinine
Albumin	Bromazepam	Cyclobenzaprine
Allobarbitol	d-Brompheniramine	Delorazepam
Alphenal	Buprenorphine	Deoxycortisone acetate
Alprazolam	Butalbital	Desipramine
Amitriptyline	Butethal	Dextromethorphan
Amobarbitol	Caffeine	Diazepam
Amoxapine	Cannabinol	Dihydrocodeine
Amoxicillin	(except THC assay)	(except OPI assay)
d-Amphetamine	Cannabidiol	4-Dimethylaminoantipyrine
(except AMP assay)	Chloral Hydrate	Diphenhydramine
d,l-Amphetamine	Chloralazepoxide	Dopamine
(except AMP assay)	Chloroquine	Doxepin hydrochloride
l-Amphetamine	d-Chlorpheniramine	Doxylamine
(except AMP assay)	Chlorpromazine	Ecgonine (except COC assay)
Ampicillin	Chloroamphetamine (DL-p-)	Ecgonine Methyl Ester
Apomorphine	Hydrochloride	(except OPI, COC assays)
Aprobarbitol	(except AMP assay)	d,l-Ephedrine
l-Ascorbic Acid	Cholesterol	l-Ephedrine
Aspartame	Clobazam	1R, 2S l-Ephedrine

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

Bibliography of Suggested Reading

- Wong, R. The Current Status of Drug Testing in the US Workforce, American Clinical Laboratory, vol. 21(1), page 21-23, 2002.
- Caplan, Y. and Goldberger, B., Alternative Specimens for Workplace Drug Testing, J. Analytical Toxicology, vol. 25, p. 396-399, 2001.
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- Mandatory Guidelines for Federal Workplace Drug Testing Programs, April 13, 2004 (69 FR 19644).
- 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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Explanation of Symbols		IVD Directive 98/79/EC	
	Caution Consult accompanying documents		Store at 15–30°C
	In vitro diagnostic		Reference Number
	Lot Number		Lot Number
	Use only once		Tests per unit
		Manufacturer acc. to IVD-Directive 98/79/EC	

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