

BEFORE PERFORMING THE TEST, PLEASE READ THESE INSTRUCTIONS CAREFULLY

## Drug of Abuse Saliva test

Rapid test for the simultaneous detection of the following drugs in saliva: morphine, heroin, amphetamine, marijuana, hashish and cocaine.

**Medical device for self-testing.**

### INTRODUCTION

Drug TEST from saliva is a rapid test for the simultaneous detection of the following drugs in saliva: morphine, heroin, amphetamine, marijuana, hashish and cocaine. The test should be used when it is not known exactly which drug was taken.

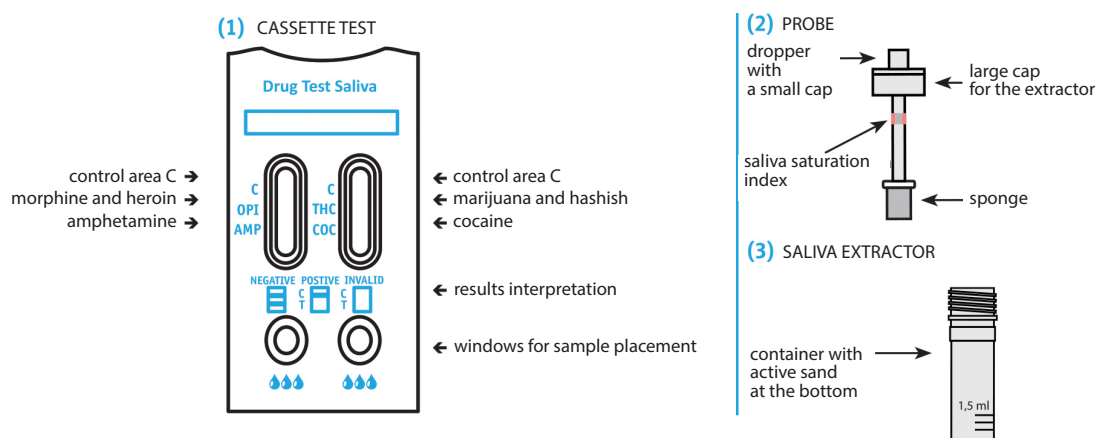
The test involves taking a saliva sample using a special probe and the sample container, then the introduction of 3 drops of saliva into each of two circular windows of the test cassette. The cassette test is composed of two test strips arranged in a plastic housing. Strip on the left detects morphine and heroin (OPI) and amphetamine (AMP). Strip on the right detects marijuana and hashish (THC) and cocaine (COC). Each strip has an internal quality control (line C in the control area). The appearance of a colored control line indicates that the test was performed correctly. Results of the test in the form of colored lines are read after 10 minutes. The saliva drug test provides information about the pathological condition caused by drug use and is therefore helpful in diagnosing drug addiction. The test is also helpful in monitoring therapeutic activities related to the treatment of these addictions.

### PACKAGE CONTENT

The package includes equipment necessary to perform one test:

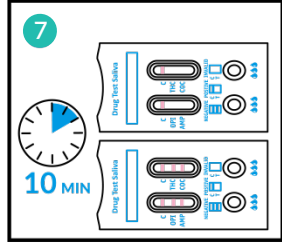
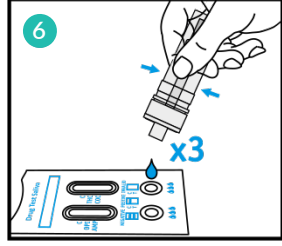
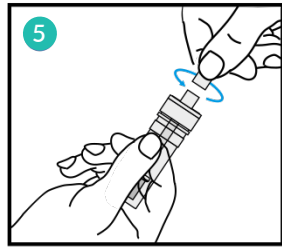
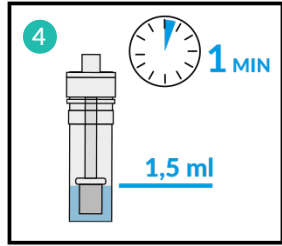
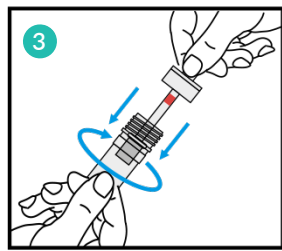
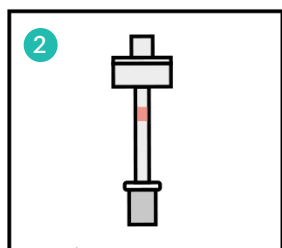
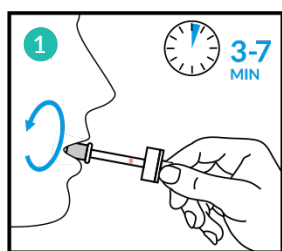
- » 1 aluminum sealed bag which contains 1 cassette test and 1 desiccant
- » 1 transparent bag which contains 1 probe for saliva collection
- » 1 aluminum sealed bag which contains 1 sample container and 1 desiccant
- » 1 instruction for use.

You need to prepare a watch that will be needed for checking the time of reading the test result.



### IMPORTANT NOTES BEFORE PERFORMING THE TEST

- » Saliva for testing can be collected at any time of the day.
- » At least 10 minutes before the test the subject should refrain from eating, drinking, chewing gum, smoking cigarettes.
- » The test must be performed immediately after collecting saliva sample.
- » Perform the test in strict compliance with the instructions below.
- » If the test was stored at 2-8°C, for half an hour before performance, remove it from the refrigerator and wait until its temperature reaches room temperature.



### TEST PERFORMANCE

» Take the probe out of the packaging and insert the end of the probe with the sponge into the mouth. Vigorously, several times rub the inside of the mouth (cheeks, tongue and gums), and hold it in mouth for 3 to 7 minutes until the sponge becomes completely saturated with saliva. Do not bite or chew sponge! ❶

» The red color of the indicator on the probe pin indicates that probe is properly soaked. ❷

» Take the saliva extractor out of the bag. Take the soaked probe out of the mouth, place it in extractor and twist the large cap by pressing the sponge firmly to the bottom. ❸

» Make sure there is at least 1,5 ml saliva collected. Let the extractor stand for 1 minute in horizontal position. ❹  
Meanwhile take the test of a bag and place it on clean and flat surface.

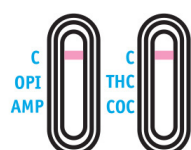
» After 1 minute of incubation, unscrew the small cap from the dropper on the sampler. ❺

» While holding the container with dispenser pointing downwards, squeeze the upper part of the container and enter 3 drops of saliva into each of two circular windows. ❻

» Read the test result after 10 minutes. ❼  
The result obtained after more than 20 minutes should not be taken into account.

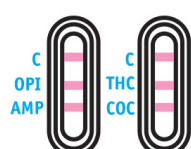
» After reading the test result, dispose of all the test components in household garbage.

### TEST RESULTS INTERPRETATION



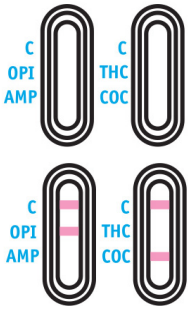
#### POSITIVE RESULT

Two colored lines appeared in control areas C of both strips. This means that the test was performed correctly. There is no colored line in the OPI, AMP, THC and COC areas. This means that the test showed the presence of opiates (morphine/heroin), amphetamine, marijuana/hashish and cocaine in saliva.



#### NEGATIVE RESULT

Two colored lines appeared in control areas C of both strips. This means that the test was performed correctly. Colored lines appeared in the OPI, AMP, THC and COC areas. This means that there were detected no opiates (morphine/heroin), no amphetamines, no marijuana/hashish and no cocaine in the saliva sample. The intensity of line's color is not important. If there is any shade of a line in a given drug test area, the result should be interpreted as negative.



### INVALID RESULT

There are no colored lines in the control areas C of both strips.

In this case, the interpretation of the test results is not possible and the test should be repeated using a new sample of saliva and a new test.

### Example :

Two colored lines appeared in control areas C of both strips. This means that the test was performed correctly. Colored lines appeared in the OPI and COC areas. This means that no opiates (morphine/heroin) and cocaine were detected in the saliva sample. There are no colored lines in the AMP and THC areas. This means that the test showed the presence of amphetamine and marihuana/hashish in the saliva.

### PRECAUTIONS

- » The test is for external use only.
- » The test should be stored at a temperature of 2–30°C. Do not freeze. Do not expose to direct sunlight.
- » Do not use after expiry date on the package.
- » Do not use the test in the case the aluminum bag is damaged, because the moisture in the air could damage the test.
- » The test is intended for one use only.
- » Remove the used test as every other household waste.
- » Keep the test out of the reach of children.
- » Do not make any decision of medical relevance without first consulting your doctor.

### PRINCIPLE OF THE TEST

Saliva drug test is an immunochromatographic test for the qualitative detection of the following drugs:

abbreviation	drug of abuse	detected substance	cut-off [ng/ml]	presence in saliva
AMP	amphetamine	D-amphetamine	50	approx. 20–50 hrs.
COC	cocaine	benzoylecgonine	20	approx. 12–24 hrs.
THC	marihuana and hashish	11-nor- $\Delta^9$ -THC-9 COOH	50	approx. 14 hrs
OPI	morphine and heroin	morphine	40	approx. 12–24 hrs.

Operation of the test is based on the highly specific reactions occurring between antigens and antibodies. The drug present in the saliva competes with the drug conjugate for binding sites on the specific antibodies coated on the test membrane.

Correct test performance is confirmed by appearance of line in control area C.

### Derivative compounds of drugs and their concentration [ng/ml], above which the test indicates a positive result after 10 min.:

- » The derivative compounds of amphetamine: D-amphetamine (50), L-amphetamine (4,000), (+) - 3,4-methylenedioxyamphetamine (MDA) (150), phentermine (40, 000), PMA (125), tyramine (3,000).
- » The derivative compounds of cocaine: benzoylecgonine (20), cocaine (20) ecgonine (4,000), methyl ester of ecgonine (10,000).
- » The derivative compounds of marihuana: 11-nor- $\Delta^9$ -THC-9 COOH (12),  $\Delta^8$ -tetrahydrocannabinol (2 000),  $\Delta^9$ -tetrahydrocannabinol (,000), 11-hydroxy-  $\Delta^9$ -THC (300).
- » The derivative compounds of the opiates: morphine (40), codeine (10), diacetylmorphine (heroin) (50), ethylmorphine (24), hydraulic drokodon (50), hydromorphone (100), 6-monoacetylmor- finals (6-MAM) (50), morphine 3-beta-D-glucuronide (50), nalorphine (10,000), oxycodone (25,000), oxymorphone (25,000), thebaine (5,000).

A study was conducted to determine the cross-reactivity of this drug of abuse saliva test with compounds and the following compounds demonstrated no false positive results when tested at concentrations up to 100 g/mL:

$\alpha$ -hydroxyalprazolam,  $\beta$ -Phenylethylamine, (-)-Cotinine, (-)-Ephedrine, (-) Isoproterenol, (+)-cis, Diltiazem, (+)-Ephedrine, (+)-Naproxen, ( $\pm$ )-Epinephrine, ( $\pm$ )-Norketamine, ( $\pm$ )-Phenylpropanolamine, 4-Dimethylaminoantipyri- ne, Acetaminophen, Acetone, Acetophenetidine, Acetylcodeine, Albumine, Alphenal, Alprazolam, Amantadine, Amikacin, Aminopyrine, Amitriptyline, Amoxicilline, Ampicilline, Apomorphine, Aspartame, Aspirin, Atenolol, Atropine, Baclofen, Barbitol, Benzocaine, Bilirubin, Butethal, Caffeine, Carba- mazepine, Cephalixin, Chloramphenicol, Chloroquine, Chlorpheniramine, Chlorprothixene, Cholesterol, Chorptothixene, Cimetidine, Ciprofloxacin, Citalopram, Clindamycin, Clobazam, Clomipramine, Clonidine, Clozapine, Creatine, Creatinine, Cyclobenzaprine, Delorazepam, Desipramine, Dexa- methasone, Diclofenac, Dicumarol, Diflunisal, Digoxin, Dihydrocodeine, Dimenhydrinate, Diphenhydramine, DL-Propranolol, DL-Tryptophan, DL-Ty- rosine, Dopamine, Doxepin, D-Propoxyphene, EDDP, Erythromycine, Estron 3 sulfate, Ethanol, Etodolac, Fentanyl, Fluoxetine, Flupentixol, Furosemide, Gastrozepin, Gentamicin, Gentsic acid, Glucose, Guaiacol Glyceril Ether, Haloperidol, Hemoglobin, Hexobarbital, Hydralazine, Hydrochlorothiazide, Hydrocortisone, Ibuprofen, Imipramine, Indomethacin, Insulin, Kanamycin, Ketamine, Ketoprofen, Lidocaine, Lincomycin, Lindane, Loperamide, Lormetazepam, L-Thyroxine, Maprotiline, Methadone, Metoclopramide, Metoprolol, Metronidazole, Midazolam, Mirtazapin, Nifedipine, Nimesulide, N-Methylephedrine, Norchloridiazepoxide, Nordoxepinhydrochloride, Nortriptyline, Olanzapine, Opipramol, Oxalic acid, Oxymetazoline, Paroxetine, Pemoline, Pennicilline G, Perphenazine, Phenothiazine, Phenytoin, Prednisolone, Prednisone, Protriptyline, Quetiapine, Quinidine, Ranitidine, Rifampicine, Risperidone, Salbutamol, Salicylic acid, Secobarbital, Sertraline, Sodium chloride, Spironolactone, Sulfamethoxazole, Sulindac, Theophylline, Thiamine, Thioridazine, Tobramycin, Triamterene, Triazolam, Trimethoprim, Trimipramine, Valproic acid, Vancomycin, Venlafaxine, Verapamil, Zolpidem.

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Version 8 AT/EN

### METHOD LIMITATIONS

- » Drug of abuse saliva test is a medical device for in vitro diagnostics intended for the detection of drugs in saliva.
- » The test provides only preliminary analytic results. To confirm the results it is necessary to conduct additional laboratory tests, the gas chromatography and/or mass spectrometry methods are recommended (GC/MS).
- » All results, especially positive, require confirmation by additional laboratory tests.
- » Failure to follow test instructions and some other substances and agents may disturb the test and provide false results.
- » Positive results only confirm the presence drug/its metabolite in the sample of saliva and do not determine the level of intoxication.
- » Negative results do not preclude the presence of drug/its metabolite in the saliva, as the concentration of drug/its metabolite may be lower than the minimum level of test detection.
- » The test does not differentiate drugs and medicines.

### FREQUENTLY ASKED QUESTIONS

#### How long after the ingestion the drugs remain in the saliva in detectable levels?

Morphine and heroin are detectable in the saliva for approx. 12-24 hrs. after ingestion, amphetamine for approx. 20-50 hrs., marihuana and hashish for approx. 14 hrs., and cocaine for approx. 12-24 hrs. The values given are approximate values. The fact how long after taking the drugs are detectable in saliva depends on many factors: the size of the dose, frequency and route of drug (intravenous, oral, nasal), the kinetics of the drug (the rate of absorption, distribution, metabolism and elimination) health condition and the weight of the person using the drugs.

#### Is it possible to read the results after 20 minutes?

No, you should not read the results after 20 minutes. Studies have shown that the results obtained after 20 minutes are unreliable.

#### Are the results obtained using saliva drug test reliable?

Yes, saliva drug test gives reliable results. Test was tested on 180 samples (150 negative and 30 positive). The following the sensitivity and specificity were obtained for the individual drugs: AMP sensitivity > 99%, specificity > 99%, COC sensitivity > 99%, specificity > 99%, OPI sensitivity > 99%, specificity > 99%, THC sensitivity > 83%, specificity > 99%.

#### What to do to be assured of getting the correct results?

To ensure that the correct results are obtained one must comply with the instruction for use and the time to read the test result.

#### What should one do if a positive result for any drug is obtained?

If there is a positive result for any drug, observe the tested person and their behavior. If the positive result is repeated, you should report to the appropriate unit for professional help.

#### Does the negative result prove beyond doubt that the person whose saliva has been tested, did not take drugs?

A negative result generally means that no drugs or their metabolites were detected in the saliva sample. However, obtaining a negative result does not always mean that the person whose saliva was tested, did not take drugs because:

- » if a long time has passed since taking the drug, its level or level of its metabolite in the saliva sample is so low that the test cannot detect it.
- » the presence of drugs in saliva depends on the size of the dose, frequency and route of drug taking (intravenous, oral, intranasal), drug kinetics (speed of absorption, distribution, metabolism and elimination), health condition, and weight of the person using the drug,
- » one cannot completely exclude the possibility of adulteration of the saliva sample.

#### What does the invalid test result mean?

In a very rare cases it may happen that after the test performance, in the control area C no colored line appears.

Most often it happens when:

- » too small sample of saliva was provided to the test,
- » instruction for use has not been complied with,
- » the test was past its expiry date.

In such cases, the result is invalid and the test should be repeated using new saliva sample and a new test in strict compliance with the instructions for use.

### SYMBOLS

	Prior to the test performance carefully read the instruction		For in vitro diagnostics
	For single use only		Store temperature 2-30°C
	Serial number		Expiry date



### Manufacturer:

Hydrex Diagnostics Sp. z o.o.  
Aleja Stanów Zjednoczonych 61A  
04-028 Warsaw, Poland  
www.hydrex.pl  
www.controly.eu