

iSCREEN™ ORAL FLUID TEST DRUG SCREEN SWAB

Catalogue No. See Box Label

For *in vitro* diagnostic use.

iSCREEN™ Oral Fluid Test Drug Screen Swab offers qualitative detection of the following drugs of abuse and their principal metabolites in human oral fluid at specified cut-off levels for use in employment and insurance testing: Amphetamine (AMP), Cocaine (COC), Methamphetamine (MET), Opiate (OPI), Oxycodone (OXY), Phencyclidine (PCP) and Marijuana (THC).

INTENDED USE AND SUMMARY

iSCREEN™ Oral Fluid Test Drug Screen Swab is a rapid oral fluid screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human oral fluid at the following cut off concentrations for use in employment and insurance testing.

Test	Calibrator	Cut off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Cocaine (COC)	Cocaine	20
Methamphetamine (MET)	D-Methamphetamine	50
Opiate (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Marijuana (THC)	Δ9-THC	40

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

The assay provides a qualitative, preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography-Mass Spectrometry (GC-MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary results are positive.

iSCREEN™ Oral Fluid Test Drug Screen Swab is a competitive immunoassay that is used to screen for the presence of drugs in oral fluid. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combine to a limited number of antibody-dye conjugate binding sites. When collection pad is immersed into the oral fluid sample, the sample is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug/protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band that, regardless of its intensity, indicates a negative result. When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the Test Region (T), indicating a potentially positive result. To serve as a procedure control, a colored band will appear at the Control Region (C) if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- Not to be used for clinical diagnosis.
- Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use the test kit beyond expiration date.

- Do not use the test if the pouch is punctured or not well-sealed.
- Keep out of the reach of children.
- Do not read results after 10 minutes.
- The used test device should be discarded according to local regulations.

CONTENT OF THE KIT

- 25 iSCREEN™ Oral Fluid Test Drug Screen Swabs
- One (1) Package Insert
- One (1) Procedure Card

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or Clock

STORAGE AND STABILITY

- Store at 39°F - 86°F (4°C - 30°C) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.
- Preferably open the pouch only shortly before collection and testing.

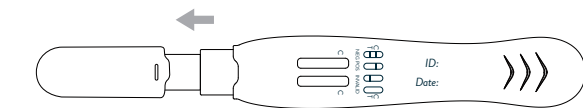
SPECIMEN COLLECTION AND PREPARATION

Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

TEST PROCEDURE

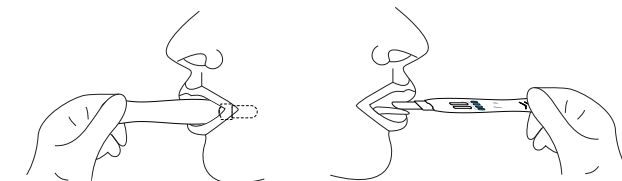
Allow the kit and specimen to come to room temperature (65°F-86°F/18°C -30°C) prior to testing. AVOID PLACING ANYTHING IN THE MOUTH 10 MINUTES PRIOR TO TESTING.

- Remove the test device from the foil pouch by tearing at the notch. Hold the grip and remove the cap to expose the collection pad.



- Place the collection pad horizontally into the mouth. Swab BOTH cheeks then the top of tongue by moving collection pad in a circular motion. Swab EACH part approximately 15-20 times.

Note: Do not chew, suck, blow, bite or bend the collection pad.

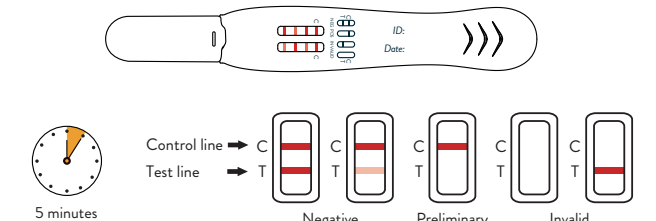


- Place the collection pad under the tongue. Keep the collection pad in place with the tip of tongue against it. Hold the test device until observe the colored bands appear in the Control Region (C), then remove the test device out of mouth.

Note: The colored band will appear within 3 minutes most of the time. If no colored band is observed after 5 minutes, repeat the test following Step 1-3 with another test device.



- Re-cap the test device and lay it on a flat surface. Read results at 5 minutes. Do not read after 10 minutes.



READING THE RESULTS

Negative (-)

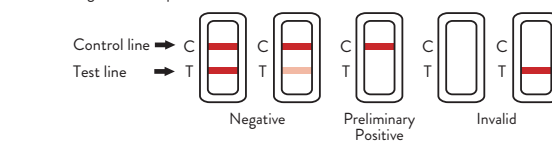
A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)

A colored band is visible in the Control Region (C). No colored band appears in the appropriate Test Region (T). It indicates a preliminary positive result for the corresponding drug of that specific test zone.

Invalid

If a colored band is not visible in the Control Region (C) or a colored band is only visible in the Test Region (T), the test is invalid. Another test should be opened and run to re-evaluate the specimen. If the new test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.



Note: There is no meaning attributed to line color intensity or width.

The preliminary positive test result does not always mean that a person took illegal drugs. The negative test result does not always mean that a person did not take illegal drugs. There could be a number of factors that affect the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

What Is the False Positive Test?

The definition of the false positive test would be an instance where a substance is identified incorrectly by iSCREEN™ Oral Fluid Test Drug Screen Swab. The most common causes of the false positive test are cross reactants. Certain foods, medicines, diet plan drugs and nutritional supplements may cause the false positive test result with this product.

What Is the False Negative Test?

The definition of the false negative test is that the initial drug is present but isn't detected by iSCREEN™ Oral Fluid Test Drug Screen Swab. If the specimen is diluted or adulterated, it may cause the false negative result.

If suspect someone is taking drugs but get the negative test results, please test again at another time, or test for different drugs.

TEST LIMITATIONS

- This test has been developed for testing oral fluid specimen only. No other fluids have been evaluated. DO NOT use this device to test substances other than oral fluid.
- It is possible that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause false results.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.

QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot, each new shipment and each new operator to determine that tests are working properly.

PERFORMANCE CHARACTERISTICS

A. Analytical Sensitivity

Standard drugs were spiked into negative PBS pool to the concentration of 0% Cut-off, -50% Cut-off, -25% Cut-off, Cut-off, +25% Cut-off and +50% Cut-off. The results were summarized below.

Drug Conc. (Cut-off Range)	N	AMP		COC		MET	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	25	5	26	4	28	2
Cut-off	30	15	15	14	16	9	21
+25% Cut-off	30	9	21	9	21	4	26
+50% Cut-off	30	0	30	0	30	0	30

Drug Conc. (Cut-off Range)	N	OPI		OXY		PCP		THC	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	26	4	28	2	30	0
Cut-off	30	16	14	14	16	17	13	9	21
+25% Cut-off	30	5	25	6	24	4	26	18	12
+50% Cut-off	30	0	30	0	30	0	30	0	30

B. Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which iSCREEN™ Oral Fluid Test Drug Screen Swab identified positive results at the read time of 5 minutes.

Drug	Concentration (ng/mL)
Amphetamine (AMP)	
D-Amphetamine	50
D,L-Amphetamine	125
β-Phenylethylamine	10000

Tryptamine	10000
(+)-3,4-Methylenedioxyamphetamine (MDA)	200
Cocaine (COC)	
Cocaine	20
Benzoylcegonine	100
Cocaethylene	200
Ecgonine methylester	50
Methamphetamine (MET)	
D-Methamphetamine	50
p-Hydroxymethamphetamine	1000
Methoxyphenamine	25000
MDEA	1000
MDMA	100
(1R,2S) - (-) Ephedrine	> 100000
Opiate (OPI)	
Morphine	40
Codeine	100
Ethyl morphine	100
Hydromorphone	1000
Hydrocodone	2000
Levorphanol	2000
Heroin	50
Thebaine	1500
Oxycodone (OXY)	
Oxycodone	20
Dihydrocodeine	4000
Codeine	10000
Hydromorphone	300000
Morphine	11000
Acetylmorphine	> 100000
Buprenorphine	> 100000
Ethyl morphine	> 100000
Phencyclidine (PCP)	
Phencyclidine	10
4-Hydroxyphencyclidine	12500
Marijuana (THC)	
Δ^9 - THC	40
Δ^8 - THC	1000
11-nor- Δ^9 -THC-9-COOH	25
11-nor- Δ^8 -THC-9-COOH	60
11-hydroxy- Δ^9 -THC	400
Cannabinol	1000

C. Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drugfree PBS stock. The following components show no cross-reactivity when tested with iSCREEN™

Oral Fluid Test Drug Screen Swab at a concentration up to 100 µg/mL.

Ketoprofen	(-) Cotinine
Acetophenetidin	Phenelzine
Loperamide	Creatinine
N-Acetylprocainamide	D,L-Propranolol
Maprotiline	Deoxycorticosterone
Acetylsalicylic Acid	D-Propoxyphene
Meprobamate	Dextromethorphan
Aminopyrine	Diclofenac
Labetalol	Quinidine
Amoxicillin	Diflunisal
Meperidine	Quinine
Ampicillin	Digoxin
Meprobamate	Ranitidine
Ascorbic Acid	Diphenhydramine
Methylphenidate	Salicylic acid
Apomorphine	Serotonin (5-Hydroxytyramine)
Nalidixic Acid	β -Estradiol
Aspartame	Sulfamethazine
Naloxone	Ethyl-p-aminobenzoate
Atropine	Sulindac
Naltrexone	Fenoprofen
Benzilic Acid	Tetracycline
Naproxen	Tetrahydrocortisone, 3 Acetate
Benzoic Acid	Gentisic Acid
Niacinamide	Thiamine
Benzphetamine	Hemoglobin
Nifedipine	Thioridazine
D,L-Brompheniramine	Hydralazine
Norethindrone	D, L-Tyrosine
Caffeine	Hydrochlorothiazide
D-Norpropoxyphene	Tolbutamide
Chloralhydrate	Hydrocortisone
Noscapine	Triamterene
Chloramphenicol	O-Hydroxyhippuric Acid
D,L-Octopamine	Trifluoperazine
Chlorothiazide	p-Hydroxytyramine
Oxalic Acid	Trimethoprim
Oxolinic Acid	Ibuprofen
Chlorpromazine	D, L-Tryptophan
Oxymetazoline	Iproniazid
Chloroquine	Tyramine
Cholesterol	Isoproterenol
Penicillin-G	Uric Acid
Clonidine	Isoxsuprine
Pentazocine	Verapamil
Cortisone	Zomepirac
Perphenazine	

ASSISTANCE

If you have any question regarding to the use of this product, please contact 1-888-669-4337.

BIBLIOGRAPHY OF SUGGESTED READING

1. Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and











Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.

2. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9.
4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201.

ADDITIONAL INFORMATION AND RESOURCES

The following list of organizations may be helpful to you for counseling support and resources. These groups also have an Internet address which can be accessed for additional information.
National Clearinghouse for Alcohol and Drug Information www.health.org 1-800-729-6686
Center for Substance Abuse Treatment www.health.org 1-800-662-HELP
The National Council on Alcoholism and Drug Dependence www.ncadd.org 1-800-NCA-CALL
American Council for Drug Education (ACDE) www.acde.org 1-800-488-DRUG

INDEX OF SYMBOLS

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 4°C-30°C (39°F-86°F)		Keep Dry
	Batch Number		Catalog #		Keep Away from Sunlight
	Unique Device Identifier				

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