iSCREEN™
ORAL FLUID TEST
DRUG SCREEN CUBE

Catalogue No. See Box Label

For in vitro diagnostic use.

iSCREEN™ Oral Fluid Test Drug Screen Cube 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), Barbiturates (BAR), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Opiate (OPI), Oxycodone (OXY) and Phencyclidine (PCP).

INTENDED USE AND SUMMARY

iSCREEN™ Oral Fluid Test Drug Screen Cube 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
Barbiturates (BAR)	Secobarbital	20
Cocaine (COC)	Cocaine	20
Marijuana (THC)	Δ9-THC	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetaminel	50
Opiate (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10

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 Cube 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 the sponge end of the collector 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

1. Not to be used for clinical diagnosis.
2. Do not swallow.
3. Discard after first use. The test cannot be used more than once.
4. Do not use the test kit beyond expiration date.
5. Do not use the test if the pouch is punctured or not well-sealed.
6. Keep out of the reach of children.
7. Do not read results after 5 minutes.
8. The used collector and cube should be discarded according to local regulations.

CONTENT OF THE KIT

- 25 iSCREEN™ Oral Fluid Test Drug Screen Cubes
- 25 Sponge Collectors
- 5 Additional Sponge Collectors
- One (1) Package Insert
- One (1) Procedure Card

MATERIAL REQUIRED BUT NOT PROVIDED

Timer or Clock

STORAGE AND STABILITY

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

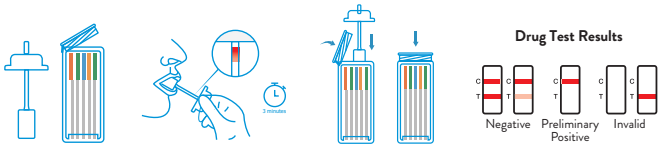
SPECIMEN COLLECTION AND PREPARATION

Use the sponge collector provided to collect the oral fluid sample. Instruct the donor not to 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 (18°C ~ 30°C/65°F ~ 86°F) prior to testing. AVOID PLACING ANYTHING IN THE MOUTH 10 MINUTES PRIOR TO TESTING.

1. Remove the test cube and the sponge collector from the foil pouch by tearing at the notch. Place the test cube upright on a level surface.
2. Put the sponge end of the collector on your tongue or near cheek to collect oral fluid for about 3 minutes until color on saturation indicator strip appears RED in the indicator window. If color on saturation indicator has not turned red after 7 minutes, repeat the collection using one additional sponge collector provided, beginning with Step 1.
3. Open the test cube and place the saturated oral fluid collector inside the test cube. Press the sponge collector down firmly until it reaches the bottom of the test cube then tightly close the cube lid. Keep test cube upright on flat surface and follow Step 4.
4. Interpreting Drug Test Results:
   Read results at 5 minutes. Do not read after 5 minutes.



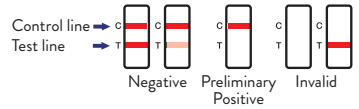
(1) (2) (3) (4)

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 Cube. 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 Cube. 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

1. 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.
2. It is possible that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause false results.
3. 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		BAR		COC		THC		MTD	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	25	5	25	5	14	16	25	5
Cut-off	30	12	18	10	20	10	20	14	16	12	18
+25% Cut-off	30	8	22	6	24	6	24	5	25	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off Range)	N	MET		MDMA		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	25	5	14	16	14	16	26	4
Cut-off	30	10	20	10	20	10	20	14	16	14	16
+25% Cut-off	30	8	22	6	24	5	25	5	25	5	25
+50% Cut-off	30	0	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 Cube identified positive results at the read time of 5 minutes.

Amphetamine (AMP)		**Methamphetamine (MET)**	
D-Amphetamine	50	D-Methamphetamine	50
D,L-Amphetamine	125	Fenfluramine	10,000
β-Phenylethylamine	4,000	p-Hydroxymethamphetamine	400
Tryptamine	1,500	Methoxyphenamine	25,000
p-Hydroxyamphetamine	800	3,4-Methylenedioxymethamphetamine	500
(+)3,4-Methylenedioxyamphetamine (MDA)	2,500	L-Phenylephrine	4,000
Methamphetamine	11,000	Procaine	2,000
3,4-Methylenedioxymethamphetamine	100,000	(1R,2S) - (-) Ephedrine	400
Dopamine hydrochloride	8,000		
		Methylenedioxymethamphetamine (MDMA)	
Barbiturates (BAR)		3,4-Methylenedioxymethamphetamine	50
Secobarbital	20	3,4-Methylenedioxyamphetamine HCl	300
Amobarbital	30	3,4-Methylenedioxyethylamphetamine	60
Alphenol	15		
Aprobarbital	20	**Opiate (OPI)**	
Butabarbital	10	Morphine	40
Butathal	10	Codeine	100
Butalbital	250	Ethyl morphine	100
Cyclopentobarbital	60	Hydromorphine	1,000
Pentobarbital	30	Hydrocodone	2,000
Phenobarbital	10	Levorphanol	400
		Morphine 3-β-D-Glucuronide	50
Cocaine (COC)		Norcodeine	1,500
Cocaine	20	Normorphine	12,500
Benzoylecgonine	100	Nalorphine	10,000
Cocaethylene	25	Oxycodone	>300,000
Ecgonine	40,000	Oxymorphone	25,000
Ecgonine methylester	12,500	Thebaine	1,500
Marijuana (THC)		**Oxycodone (OXY)**	
11-nor-Δ9-THC-9-COOH	25	Oxycodone	20
11-nor-Δ8-THC-9-COOH	60	Dihydrocodeine	4,000
11-hydroxy-Δ9-THC	2,500	Codeine	10,000
Δ8-THC	7,500	Hydromorphone	300,000
Δ9-THC	40	Morphine	11,000
Cannabinol	1,000	Acetylmorphine	> 100,000
Cannabidiol	10,000	Buprenorphine	> 100,000
		Ethyl morphine	> 100,000
Methadone (MTD)			
Methadone	30	**Phencyclidine (PCP)**	
Doxylamine	5,000	Phencyclidine	10
		4-Hydroxyphencyclidine	12,500

C. Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following components show no cross-reactivity when tested with iSCREEN™ Oral Fluid Test Drug Screen Cube at a concentration up to 100 µg/mL.

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

ASSISTANCE

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

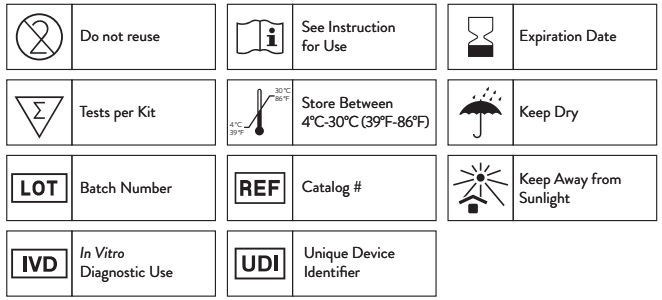
BIBLIOGRAPHY OF SUGGESTED READING

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



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