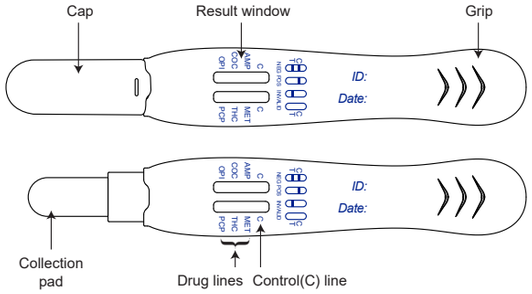
T-Swab® One Step Multi-Drug Oral Fluid Test



For *in vitro* diagnostic use.

T-Swab® One Step Multi-Drug Oral Fluid Test 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), Methylenedioxymethamphetamine (MDMA), Methamphetamine (MET), Methadone (MTD) , Opiate (OPI),Oxycodone (OXY), Phencyclidine (PCP), Marijuana (THC).

INTENDED USE

T-Swab® One Step Oral Fluid Drug Test 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:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Cocaine (COC)	Cocaine	20
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetaminel	50
Methamphetamine (MET)	D-Methamphetamine	50
Methadone (MTD)	Methadone	30
Opiate (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Marijuana (THC)	Δ9-Tetrahydrocannabinol	40

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.

Amphetamine (AMP): Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion.

Cocaine (COC): Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using. Cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating.

Methylenedioxymethamphetamine (MDMA): Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users.

Methamphetamine (MET): Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion.

Methadone (MTD): Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addict. The drug is often administered orally or intravenously and is metabolized in the liver and excreted in urine.

Opiates (OPI): The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. The principal metabolites of opiates are morphine, morphine-3-glucuroride, normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the saliva of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the saliva indicates heroin, morphine and/or codeine use. The window of detection varies for different opiates. Codeine can be detected within one hour and up to 7-21 hours after a single oral dose. Morphine is detectable for several days after a dose.

Oxycodone (OXY): Oxycodone is known as Oxycontin, Roxicodone and is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, oxycodone is characterized by its analgesic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and cardiac arrest.

Phencyclidine (PCP): Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as “angel dust” and “crystal cyclone,” etc. Phencyclidine can be administered orally, by nasal ingestion, smoking, or by intravenous injection.

Marijuana (THC): Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.

PRINCIPLE

(1) Drug Test

T-Swab® One Step Multi-Drug Oral Fluid Test 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 collection pad of T-Swab® 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, 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.

PRECAUTIONS

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

MATERIAL

Materials Provided

- 25 Individually pouched test devices with caps
- One (1) Package Insert
- One (1) Procedure Card

Material Required but Not Provided

- Timer

STORAGE AND STABILITY

1. Store at 4ºC - 30ºC (39ºF - 86ºF) 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

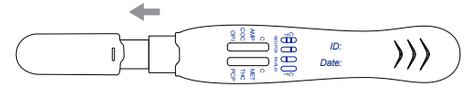
Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

TEST PROCEDURE

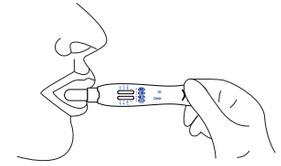
Test devices must be at room temperature((59°F-86°F)15°C -30°C) before testing.

AVOID PLACING ANYTHING IN THE MOUTH 10 MINUTES PRIOR TO TESTING.

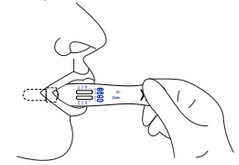
1. Holding the grip of the device.
2. Remove the blue cap to expose the collection pad.



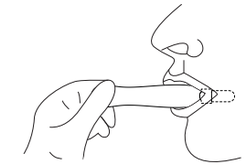
3. Place the collection pad into mouth horizontally.



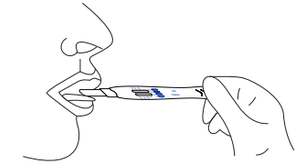
A. Rub the collection pad inside mouth against one cheek gently in a circular motion several times (approximately 15-20).



B. Keep it horizontal still, gently rub the collection pad against the opposite cheek in a circular motion several times (approximately 15- 20).

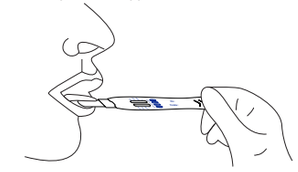


C. Rub the collection pad on top of the tongue several times (approximately 15-20).

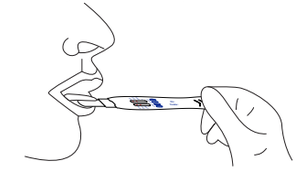


Note: Do not chew, suck, blow, bite or bend the collection pad.

4. Place the collection pad under your tongue and press the tip of your tongue against the collection pad until red liquid lines appear in both result windows.



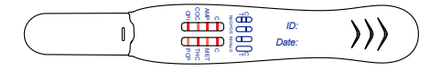
5. Hold the device in place by hand until red liquid appears in both result windows.



6. Remove the device from mouth as soon as red liquid appears in both result windows.
Note: The majority of the red liquid will appears in both result windows within 1 minutes. If no red liquid is observed in both test window after 5 minutes, discard the device, review procedures 1-5 above with the donor and repeat the test using a new device.

7. Re-cap the device, lay it on a flat surface and start timing. **Read results at 5-10 minutes. Do not read after 10 minutes.**


5-10 minutes



INTERPRETATION OF RESULTS

Negative (-)

A colored line in the Control Region (C) and another line in the Test Region (T) indicate that the respective drug is not present, or that the drug concentration in the oral fluid specimen is below the designated cutoff level for that drug.

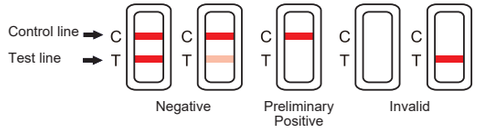
Preliminary Positive (+)

A colored band is visible in the Control Region (C). No color band appears in the

appropriate test region. It indicates a positive result for the corresponding drug of that specific Test Region (T). Preliminary positive results should be confirmed with a more specific method before positive determinations are made.

Invalid

If a colored band is not visible in the Control Region (C), the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor with the lot number.



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

QUALITY CONTROL

Though there is an internal procedural control line in the test device of 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 control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. The test provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

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		MDMA		MET		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	25	5	26	4	24	6	28	2	25	5
Cut-off	30	15	15	14	16	19	11	9	21	18	12
+25% Cut-off	30	9	21	9	21	8	22	4	26	7	23
+50% Cut-off	30	0	30	0	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 T-Swab® One Step Multi-Drug Oral Fluid Test identified positive results at the read time of 5 minutes.

Amphetamine（AMP）	
D-Amphetamine	50
D,L-Amphetamine	125
β-Phenylethylamine	10000
Tryptamine	10000
MDA	200
Cocaine (COC)	
Cocaine	20
Benzoylecgonine	100
Cocaethylene	200
Ecgonine methylester	50
Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxymethamphetamine	50
3,4-Methylenedioxyamphetamine HCl	300
3,4-Methylenedioxyethylamphetamine	60
Methamphetamine (MET)	
D-Methamphetamine	50
p-Hydroxymethamphetamine	1000
Methoxyphenamine	25000
MDEA	1000
MDMA	100
(1R,2S) - (-) Ephedrine	> 100000
Methadone (MTD)	
Methadone	30
Doxylamine	5000
Opiate (OPI)	
Morphine	40
Codeine	100
Ethyl morphine	100
Hydromorphone	1000
Hydrocodone	2000
Levorphano	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)	
△9- THC	40
△8- THC	1000
11-nor-△9-THC-9-COOH	25
11-nor-△8-THC-9-COOH	60
11-hydroxy-△9-THC	400
Cannabinol	1000

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 T-Swab® One Step Multi-Drug Oral Fluid Test 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	

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.
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4. McCarron, MM, et al, “Detection of Phencyclidine Usage by Radioimmunoassay of Saliva,"J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201.

INDEX OF SYMBOLS


Keep away from sunlight

Store between 4°C - 30°C (39°F - 86°F)


Keep dry


Do not re-use

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