T-Cube® One Step Oral Fluid Drug Test

For in vitro diagnostic use.

T-Cube® One Step Oral Fluid Drug 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), Barbiturates (BAR), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Opiate (OPI), Oxycodone (OXY) and Phencyclidine (PCP).

INTENDED USE

T-Cube® 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 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)	∆ 9- THC	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Methylenedioxymethampheta mine (MDMA)	3,4-Methylenedioxymetham phetaminel	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.

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

Barbiturates (BAR): Barbiturates are a class of central nervous system depressants. Abuse of barbiturates can lead not only to impaired motor coordination and mental disorder, but also to respiratory collapse, coma and even death. Barbiturates are taken orally, rectally, or by intravenous and intramuscular injections.

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.

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.

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.

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.

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.

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.

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.

PRINCIPLE

T-Cube® One Step Oral Fluid Drug 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 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, 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. 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 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.

MATERIAL

Materials Provided

- 25 Test Cubes
- 25 Sponge Collectors
- 5 Additional Sponge Collectors
- One (1) Package Insert

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.

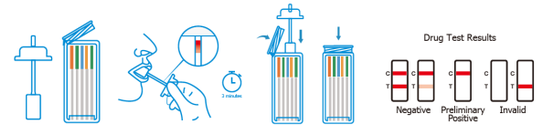
SPECIMEN COLLECTION AND PREPARATION

Collect the oral fluid sample using the sponge collector provided. 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.

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 at 7 minutes, repeat the collection 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 Step4.
4. Interpreting Drug Test Results:
   Read results at 5 minutes. Do not read after 5 minutes.



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

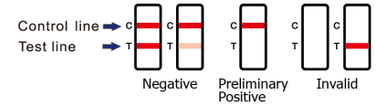
INTERPRETATION OF RESULTS

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 color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific Test Region (T).

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		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	14	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 T-Cube® One Step Oral Fluid Drug Test 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
ß-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- ∆ 9-THC-9-COOH	25	Oxycodone	20
11-nor- ∆ 8-THC-9-COOH	60	Dihydrocodeine	4,000
11-hydroxy- ∆ 9-THC	2,500	Codeine	10,000
∆ 8- THC	7,500	Hydromorphone	300,000

∆9- 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 T-Cube® One Step Oral Fluid Drug Test 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

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.

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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