T-Square™ One Step Multi-Drug Oral Fluid Test

For in vitro diagnostic use.

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

INTENDED USE

T-Square™ One Step Multi-Drug Oral Fluid Test 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
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-THC	40

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.

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.

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-Square™ One Step Multi-Drug Oral Fluid Test 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.

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 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 (65°F-86°F/18°C-30°C) prior to testing. AVOID PLACING ANYTHING IN THE MOUTH 10 MINUTES PRIOR TO TESTING.

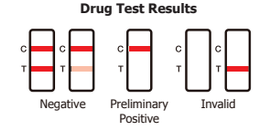
1. Remove the test cube and the sponge collector from the foil pouch by tearing at the notch. Place the test cube upright on a level surface.

2. Put the sponge end of the collector in your mouth to collect oral fluid for about 7 minutes or until the sponge is fully saturated by oral fluid. Do not chew, bite or suck the sponge. If the amount of oral fluid does not make the sponge fully saturated within 7 minutes, repeat the collection using one additional sponge collector provided, beginning with Step 1.
   Note: In case of the dry mouth, do not swallow oral fluid during collection.

3. Open the test cube and place the fully saturated sponge collector inside the test cube. Press the sponge collector down firmly until it reaches the bottom of the test cube, then close the cube lid tightly while compressing the collector. Keep test cube upright on flat surface and follow Step 4.
   Note: Make sure the sponge collector is inserted vertically and the handle of collector is put into the clamp.

4. Interpreting Drug Test Results:
   Read results at 5 minutes. Do not read after 5 minutes.

(1) (2) (3)



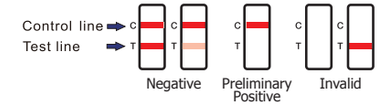
(4)

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 colored band appears in the appropriate Test Region (T). 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		MDMA		MET	
		-	+	-	+	-	+	-	+	-	+
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	25	5	28	2
Cut-off	30	12	18	10	20	10	20	10	20	10	20
+25% Cut-off	30	8	22	6	24	6	24	6	24	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off Range)	N	MTD		OPI		OXY		PCP		THC	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	30	30	0	30	0	30	0
-25% Cut-off	30	25	5	14	16	14	16	26	4	14	16
Cut-off	30	12	18	10	20	14	16	14	16	14	16
+25% Cut-off	30	6	24	5	25	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-Square™ One Step Multi-Drug Oral Fluid Test Cube identified positive results at the read time of 5 minutes.

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

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-Square™ One Step Multi-Drug Oral Fluid Test 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
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
(-) 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
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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