T-Square Multi-Drug Oral Fluid Test

Catalogue No. See Box Label

For in vitro diagnostic use.

SAFElife™ T-Square 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), Barbiturates (BAR), Cocaine (COC), Methylenedioxymethamphetamine (MDMA), Methamphetamine (MET), Methadone (MTD), Opiate (OPI), Oxycodone (OXY), Phencyclidine (PCP) and Marijuana (THC).

INTENDED USE

SAFElife™ T-Square Multi-Drug Oral Fluid 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
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.

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

SAFElife™ T-Square 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 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 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.

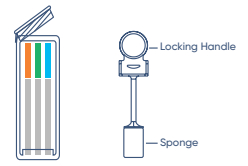
SPECIMEN COLLECTION AND PREPARATION

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.

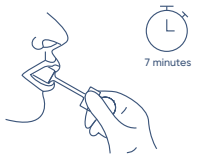
TEST PROCEDURE

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)



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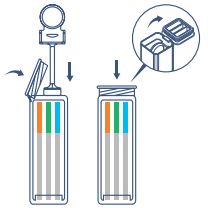
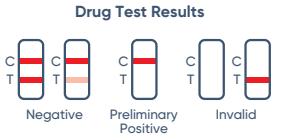


(3)



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

(4)

INTERPRETATION OF RESULTS

Negative (-)

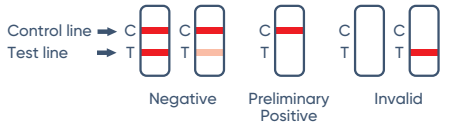
A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

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	0	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 SAFElife™ T-Square Multi-Drug Oral Fluid Test 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 SAFElife™ T-Square Multi-Drug Oral Fluid 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.

ASSISTANCE

If you have any question regarding to the use of this product, please call our Toll Free Number 1-888-444-3657 (9:30 a.m. to 5:00 p.m. CDT M-F).

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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545 Willowbrook Centre Parkway, Unit B
Willowbrook, IL 60527
www.wondfousa.com

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