



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-Methylenedioxymethamphetamine	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

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

MATERIAL

Materials Provided

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

Material Required but Not Provided

- Timer

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

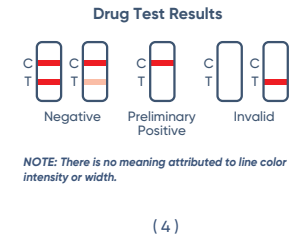
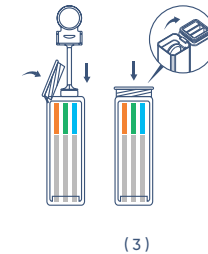
Collect the oral fluid sample using the sponge collector provided. Instruct the donor not to place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection. No other collection devices should be used with this assay. Oral fluid collected at any 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.

- 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.
- 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 using one additional sponge collector provided, beginning with Step 1.
Note: In case of the dry mouth, do not swallow oral fluid during collection.
- 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.
- Interpreting Drug Test Results:

Read results at 5 minutes. Do not read after 5 minutes.



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

INTERPRETATION OF RESULTS

Negative (-)

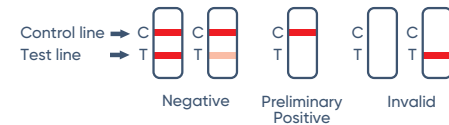
A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

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

- 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.

- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- 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	Hydromorphone	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
Benzoylcegonine	100	Acetylmorphine	>100,000
Cocaethylene	25	Buprenorphine	>100,000
Ecgonine	40,000	Ethyl morphine	>100,000
Ecgonine methylester	12,500		
		Phencyclidine (PCP)	
		Phencyclidine	10
Methylenedioxyamphetamine (MDMA)		4-Hydroxyphencyclidine	12,500
3,4-Methylenedioxyamphetamine	50		
3,4-Methylenedioxyamphetamine HCl	300		
3,4-Methylenedioxyethylamphetamine	60	Marijuana (THC)	
		11-nor-Δ9-THC-9-COOH	25
		11-nor-Δ8-THC-9-COOH	60
Methamphetamine (MET)		11-hydroxy-Δ9-THC	2,500
D-Methamphetamine	50	Δ8-THC	7,500
Fenfluramine	10,000	Δ9-THC	40
p-Hydroxymethamphetamine	400	Cannabinol	1,000
Methoxyphenamine	25,000	Cannabidiol	10,000
3,4-Methylenedioxyamphetamine	500		
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	Diffunilal
Acetophenetidin	Digoxin
N-Acetylprocainamide	Diphenhydramine
Acetylsalicylic Acid	(-) Ephedrine
Aminopyrine	β -Estradiol
Amoxicillin	Ethyl-p-aminobenzoate
Ampicillin	Fenoprofen
Ascorbic Acid	Furosemide
Apomorphine	Gentisic Acid
Aspartame	Hemoglobin
Atropine	Hydralazine
Benzilic Acid	Hydrochlorothiazide
Benzoic Acid	Hydrocortisone
Benzphetamine	O-Hydroxyhippuric Acid
D,L-Brompheniramine	p-Hydroxytyramine
Caffeine	Ibuprofen
Chloralhydrate	Iproniazid
Chloramphenicol	Isoproterenol
Chlorothiazide	Isoxsuprine
(±) Chlorpheniramine	Ketamine
Chlorpromazine	Ketoprofen
Chloroquine	Loperamide
Cholesterol	Maprotiline
Clonidine	Meprobamate
Cortisone	Labetalol
(-) Cotinine	Meperidine
Creatinine	Meprobamate
Deoxycorticosterone	Methylphenidate
Dextromethorphan	Nalidixic Acid
Diclofenac	Naloxone

Naltrexone	Quinine
Naproxen	Ranitidine
Niacinamide	Salicylic acid
Nifedipine	Serotonin (5-Hydroxytyramine)
Norethindrone	Sulfamethazine
D-Norpropoxyphene	Sulindac
Noscapine	Tetracycline
D,L-Octopamine	Tetrahydrocortisone, 3 Acetate
Oxalic Acid	Thiamine
Oxolinic Acid	Thioridazine
Oxymetazoline	D, L-Tyrosine
Papaverine	Tolbutamide
Penicillin-G	Triamterene
Pentazocine	Trifluoperazine
Perphenazine	Trimethoprim
Phenelzine	D, L-Tryptophan
D,L-Propranolol	Tyramine
D-Propoxyphene	Uric Acid
D-Pseudoephedrine	Verapamil
Quinidine	Zomepirac




BIBLIOGRAPHY OF SUGGESTED READING

- 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.
- Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
- Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9.
- 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 39°F - 86°F (4°C - 30°C)
	Keep dry
	Do not re-use

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

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