

INTERPRETATION OF RESULTS

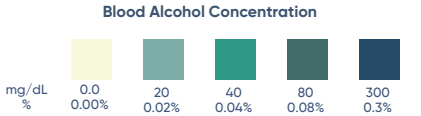
(1) Alcohol test results:

Negative (-)

No color change by comparing with the background. The negative result indicates that the BAC is less than 0.02%.

Positive (+)

A distinct color developed all over the pad. The positive result indicates that the BAC is 0.02% or higher. The alcohol concentrations are related to the colored chart below.



NOTE: Results after more than 2 minutes may be not accurate.

Invalid

The test should be considered invalid if color only develops on the edge of the pad. The subject should be re-tested.

(2) Drug test results:

Negative (-)

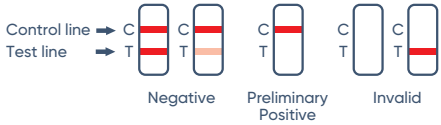
A colored band is visible in the Control Region (C) and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Preliminary Positive (+)

A colored band is visible in the Control Region (C). No colored band appears in the appropriate test region. 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		BUP		BZO		COC		FTY		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	25	5	26	4	26	4	25	5	25	5	25	5
Cut-off	30	12	18	10	20	14	16	10	20	10	20	11	19	10	20
+25% Cut-off	30	8	22	6	24	5	25	5	25	6	24	5	25	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off Range)	N	MET		MTD		OPI		OXY		PCP		THC	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	25	5	14	16	14	16	26	4	14	16
Cut-off	30	10	20	12	18	10	20	14	16	14	16	14	16
+25% Cut-off	30	8	22	6	24	5	25	5	25	5	25	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

For the alcohol test:

Oral fluid was obtained by rinsing with positive ethanol control solutions at various B.A.C (0.02%, 0.08%, 0.30%). Negative oral fluid was used to test at 0.00% concentration. For each concentration, a total of 30 tests were performed to validate the test performance.

Test	n	B.A.C							
		0.00%		0.02%		0.08%		0.30%	
		-	+	-	+	-	+	-	+
Alcohol	30	30	0	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)		Methylenedioxymethamphetamine (MDMA)	
D-Amphetamine	50	3,4-Methylenedioxymethamphetamine	100
D,L-Amphetamine	125	3,4-Methylenedioxyamphetamine HCl	300
β-Phenylethylamine	4000	3,4-Methylenedioxyethylamphetamine	60
Tryptamine	1,500		
p-Hydroxyamphetamine	800	Methamphetamine (MET)	
(+)-3,4-Methylenedioxyamphetamine (MDA)	2,500	D-Methamphetamine	50
Methamphetamine	11,000	Fenfluramine	10,000
3,4-Methylenedioxymethamphetamine	100,000	p-Hydroxymethamphetamine	400
Dopamine hydrochloride	8,000	Methoxyphenamine	25,000
		3,4-Methylenedioxymethamphetamine	500
Barbiturates (BAR)		L-Phenylephrine	4,000
Secobarbital	60	Procaine	2,000
Amobarbital	30	(1R,2S) - (-) Ephedrine	400

Alphenol	15		
Aprobarbital	20	Methadone (MTD)	
Butabarbital	10	Methadone	30
Butathal	10	Doxylamine	5,000
Butalbital	250		
Cyclopentobarbital	60	Opiate (OPI)	
Pentobarbital	30	Morphine	40
Phenobarbital	10	Codeine	100
		Ethyl morphine	100

Buprenorphine (BUP)		Hydromorphone	1,000
Buprenorphine	5	Hydrocodone	2,000
Buprenorphine-3-D-Glucuronide	10	Levorphanol	400
Norbuprenorphine	10	Morphine 3-β-D-Glucuronide	50
Norbuprenorphine3-D-Glucuronide	10	Norcodeine	1,500
		Normorphine	12,500

Benzodiazepines (BZO)		Nalorphine	10,000
Oxazepam	30	Oxycodone	>300,000
Alprazolam	50	Oxymorphone	25,000
α-Hydroxyalprazolam	300	Thebaine	1,500

Bromazepam	50		
Chlordiazepoxide	10	Oxycodone (OXY)	
Clobazam	45	Oxycodone	20
Clonazepam	1,000	Dihydrocodeine	4,000
Clorazepate dipotassium	50	Codeine	10,000
Delorazepam	1,000	Hydromorphone	300,000
Desalkylflurazepam	150	Morphine	11,000
Diazepam	500	Acetylmorphine	>100,000
Estazolam	25	Buprenorphine	>100,000
Flunitrazepam	1,000	Ethyl morphine	>100,000
D,L-Lorazepam	100		

Midazolam	1,000	Phencyclidine (PCP)	
		Phencyclidine	10
Cocaine (COC)		4-Hydroxyphencyclidine	12,500
Cocaine	20		

Benzoylcegonine	100	Marijuana (THC)	
Cocaethylene	25	11-nor-Δ9-THC-9-COOH	25
Ecgonine	40,000	11-nor-Δ8-THC-9-COOH	60
Ecgonine methylester	12,500	11-hydroxy-Δ9-THC	2,500
		Δ8- THC	7,500

Fentanyl (FTY)		Δ9- THC	40
Norfentanyl	30	Cannabinol	1,000
Fentanyl	100	Cannabidiol	10,000
Buspione	13,000		

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	β-Estradiol	Oxalic Acid
Acetophenetidin	Ethyl-p-aminobenzoate	Oxolinic Acid
N-Acetylprocainamide	Fenoprofen	Oxymetazoline
Acetylsalicylic Acid	Furosemide	Papaverine
Aminopyrine	Gentisic Acid	Penicillin-G
Amoxicillin	Hemoglobin	Pentazocine
Ampicillin	Hydralazine	Perphenazine
Ascorbic Acid	Hydrochlorothiazide	Phenelzine
Apomorphine	Hydrocortisone	D,L-Propranolol
Aspartame	O-Hydroxyhippuric Acid	D-Propoxyphene
Atropine	p-Hydroxytyramine	D-Pseudoephedrine
Benziic Acid	Ibuprofen	Quinidine

Benzoic Acid	Iproniazid	Quinine
Benzphetamine	Isoproterenol	Ranitidine
D,L-Brompheniramine	Isoxsuprine	Salicylic acid
Caffeine	Ketamine	Serotonin (5-Hydroxytyramine)
Chloralhydrate	Ketoprofen	Sulfamethazine
Chloramphenicol	Loperamide	Sulindac
Chlorothiazide	Maprotiline	Tetracycline
(±) Chlorpheniramine	Meprobamate	Tetrahydrocortisone, 3 Acetate
Chlorpromazine	Labetalol	Thiamine
Chloroquine	Meperidine	Thioridazine
Cholesterol	Meprobamate	D, L-Tyrosine
Clonidine	Methylphenidate	Tolbutamide
Cortisone	Nalidixic Acid	Triamterene
(-) Cotinine	Naloxone	Trifluoperazine
Creatinine	Naltrexone	Trimethoprim
Deoxycorticosterone	Naproxen	D, L-Tryptophan
Dextromethorphan	Niacinamide	Tyramine
Diclofenac	Nifedipine	Uric Acid
Diffunisal	Norethindrone	Verapamil
Digoxin	D-Norpropoxyphene	Zomepirac
Diphenhydramine	Noscapine	
(-)-Ephedrine	D,L-Octopamine	

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 4°C - 30°C (39°F - 86°F)
- Keep dry
- Do not re-use

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