One Step Multi-Drug Oral Fluid Test Cassette

A rapid one step test for the qualitative detection of the following drugs of abuse and their principal metabolites in human oral fluid at specified cut off level: Amphetamine (AMP), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methamphetamine (MET), Opiate (OPI).

For healthcare professional use only, For in vitro diagnostic use.

INTENDED USE

One Step Multi-Drug Oral Fluid Test Cassette is consisted of 6 individual one-step immunoassays. 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:

Test	Calibrator	Cut off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	50
Benzodiazepines(BZO)	Oxazepam	30
Cocaine (COC)	Benzoylecgonine	20
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	50
Methamphetamine (MET)	D-Methamphetamine	50
Opiate (OPI)	Morphine	40

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

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

BZO: Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders.

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca).

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.

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.

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 Opiate. 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.

This assay provides only a preliminary test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive.

PRINCIPLE

One Step Multi-Drug Oral Fluid Test Cassette is a competitive immunoassay that is used to screen for the presence of drugs of abuse in oral fluid. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites.

When the sample is added to the sample well, 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 Test line 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 line will appear at the Control Region (C), if the test has been performed properly.

PRECAUTIONS

1. This kit is for in vitro use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read results after 5 minutes.
7. The used collector and device should be discarded according to local regulations.

MATERIAL

Material provided

- Test devices
- Collection vials
- Sponge collectors
- Package insert

Material Required But Not Provided

- Timer

STORAGE AND STABILITY

1. Store at 4 ºC ~30 ºC 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 the test.

SPECIMEN COLLECTION AND PREPARATION

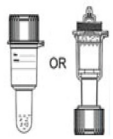
Collect the oral fluid sample using the sponge collector and collection vial provided. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

1. Insert the sponge end of the collector into the mouth. Actively swab the inside of the mouth and tongue to collect oral fluid for 3 minutes until the sponge becomes fully saturated. No hard spots should be felt on the sponge when saturated.
2. Open the top of the collection vial then remove the saturated oral fluid collector from the mouth and place it into the collection vial. Press the sponge fully against the strainer to extract as much oral fluid as possible into the collection vial.
3. Discard the collector. Cover the cap tightly as shown and mix contents by gently swirling.

Step 1:

Step 2:

Step 3:

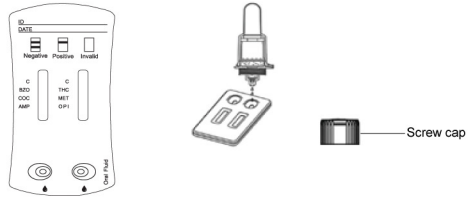


If specimen can't be tested immediately, it's recommended that specimen be stored at 2ºC~8°C for up to forty-eight hours. For longer storage, freeze the samples (-20°C or below). Bring frozen or refrigerated samples to room temperature before testing.

TEST PROCEDURE

Allow the device and specimen to equilibrate to room temperature (10°C ~30°C) prior to testing.

1. Remove a testing device from the foil pouch by tearing at the notch and place it on a level surface.
2. Twist to open the screw cap of the collection vial and don't open the inside cap of the collection vial. Add 3 drops (80~100 μL) of the oral fluid specimen into each sample well of the test device.
3. Read results in 5 minutes. **Do not read after 5 minutes.**



INTERPRETATION OF RESULTS

Positive (+)

A color band is visible in the control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

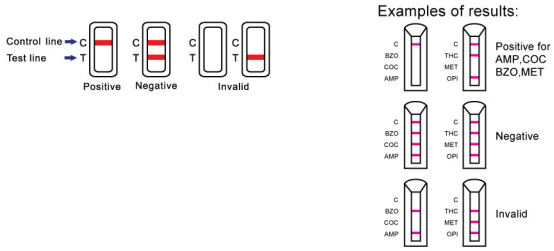
Negative (-)

A color band is visible in the control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

Invalid

If a color band is not visible in the control region, the test is invalid. Another test should be run to re-evaluate the specimen. If test still fails, please contact the distributor or manufacturer 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, 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 analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is 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 -50% cutoff, -25% cutoff, cutoff, +25% cutoff and +50% cutoff. The results were summarized below.

Drug Conc. (Cut-off range)	n	AMP		BZO		COC	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	28	2	26	4	26	4
Cut-off	30	12	18	10	20	14	16
+25% Cut-off	30	8	22	5	25	5	25
+50% Cut-off	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC		MET		OPI	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	14	16	28	2	26	4
Cut-off	30	14	16	10	20	12	18
+25% Cut-off	30	5	25	8	22	5	25
+50% Cut-off	30	0	30	0	30	0	30

B. Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the One Step Multi-Drug Oral Fluid Test identified positive results at a read time of 5 minutes.

Amphetamine		**Marijuana**	
D-Amphetamine	50	11-nor-Δ^9-THC-9-COOH	50
D.L-Amphetamine	125	11-nor-Δ^8-THC-9-COOH	30
ß-Phenylethylamine	4,000	11-hydroxy-Δ^9-THC	2,500
Tryptamine	1,500	Δ^8- THC	7,500
p-Hydroxyamphetamine	800	Δ^9- THC	10,000
(+)3,4-Methylenedioxyamphetamine (MDA)	150	Cannabinol	10,000
		Cannabidiol	100,000
Benzodiazepines			
Oxazepam	30	**Methamphetamine**	
Alprazolam	25	D-Methamphetamine	50
α-Hydroxyalprazolam	300	Fenfluramine	60,000
Bromazepam	300	p-Hydroxymethamphetamine	400
Chlordiazepoxide	300	Methoxyphenamine	25,000
Clonazepam HCl	30	3,4-Methylenedioxymethamphetamine (MDMA)	50
Clobazam	50	L-Phenylephrine	4,000
Clonazepam	30	Procaine	2,000
Clorazepate dipotassium	100	(1R,2S) - (-) Ephedrine	400
Delorazepam	300		
Desalkylflurazepam	150	**Opiate**	
Diazepam	20	Morphine	40
Estazolam	500	Codeine	10
Flunitrazepam	50	Ethylmorphine	24
D,L-Lorazepam	200	Hydromorphine	100
Midazolam	12，500	Hydrocodone	100
		Levorphanol	400
Cocaine		Morphine 3-β-D-Glucuronide	50
Benzoylecgonine	20	Norcodeine	1,500
Cocaine HCl	20	Normorphine	12,500
Cocaethylene	25	Nalorphine	10,000
Ecgonine HCl	1,500	Oxycodone	25,000
Ecgonine methylester	12,500	Oxymorphone	25,000
		Thebaine	1,500
		Diacetylmorphine (Heroin)	50

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 One Step Multi-Drug Oral Fluid Test at a concentration up to 100µg/ml.

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amobarbital
Amoxicillin
Ampicillin
Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine
D,L -Brompheniramine
Caffeine
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clonidine
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
(-)-Ψ-Ephedrine
β-Estradiol
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Loperamide
Maprotiline
Meprobamate
Methadone
Methoxyphenamine
(+) 3,4-Methylenedioxyamphetamine
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-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Serotonin (5- Hydroxytyramine)
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone, 3 Acetate
Thiamine
Thioridazine
D, L-Tyrosine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxytyramine
Ibuprofen
Iproniazid
Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
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

	See instruction for use		Tests per kit		Manufacturing date
IVD	For *in vitro* diagnostic use only		Expiry date		Do not reuse
	Store between 4 ~ 30 ℃	LOT	Batch number	REF	Catalog #
	Keep away from sunlight		Keep dry	EC REP	Authorized Representative