One Step Multi-Drug Oral Fluid Test

Catalogue No. See Box Label

For Forensic Use Only.

Prime Screen® One Step 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: Amphetamine (AMP), Barbiturates (BAR), Buprenorphine (BUP), Benzodiazepines (BZO), Cocaine (COC), Fentanyl (FTY), Methylenedioxymetham-phetamine (MDMA), Methamphetamine (MET), Methadone (MTD), Opiate (OPI), Oxycodone (OXY), Phencyclidine (PCP), Marijuana (THC) and Alcohol (ACL).

INTENDED USE

Prime Screen® One Step 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.

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Barbiturates (BAR)	Secobarbital	60
Buprenorphine (BUP)	Buprenorphine	5
Benzodiazepines (BZO)	Oxazepam	30
Cocaine (COC)	Cocaine	20
Fentanyl (FTY)	Norfentanyl	30
Methylenedioxymethampheta mine (MDMA)	3,4-Methylenedioxymethamphe taminel	100
Methamphetamine (MET)	D-Methamphetamine	50
Methadone (MTD)	Methadone	30
Opiate (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	25
Alcohol (ACL)	Alcohol	>0.02% B.A.C

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.

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.

Buprenorphine (BUP): Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence.

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

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.

Fentanyl (FTY): Fentanyl is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It was first synthesized by Janssen Pharmaceutical (Belgium) in the late 1950s, and it is approximately 100 times more potent than morphine. Fentanyl is a strong agonist at the μ-opioid receptors. Historically it has been used to treat breakthrough pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. Fentanyl is frequently given intrathecally as part of spinal anesthesia or epidurally for epidural anesthesia and analgesia.

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.

Alcohol (ACL): Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The blood alcohol concentration (BAC) at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut off level at which an individual is considered positive for the presence of alcohol.

PRINCIPLE

(1) Drug test:

Prime Screen® One Step 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, 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.

(2) Alcohol test:

It is based on the high specificity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

$$\text{EtOH} + \text{TMB} \xrightarrow{\text{ALOx/Peroxidase}} \text{CH}_3\text{CHO} + \text{Colored TMB}$$

The distinct color on reactive pad could be observed in less than 20 seconds after the absorbent end was contacted with oral fluid samples with the ethyl alcohol concentration greater than 0.02%. Other alcohols such as methyl, propany and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in oral fluid.

PRECAUTIONS

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

MATERIAL

Materials Provided

- Test Cubes
- Additional Sponge Collectors
- Procedure Card
- Sponge Collectors
- 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.

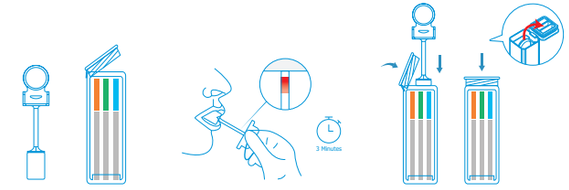
1. Remove the test cube and the sponge collector from the foil pouch by tearing at the notch. Place the test cube upright on a level surface.

2. Put the sponge end of the collector 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.

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.

4-1. Interpreting Alcohol Test Result:
Read result at 2 minutes. Do not read after 2 minutes.

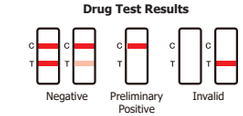
4-2. Interpreting Drug Test Results:
Read results at 5 minutes. Do not read after 5 minutes.



(1) (2) (3)

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

(4-1)



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

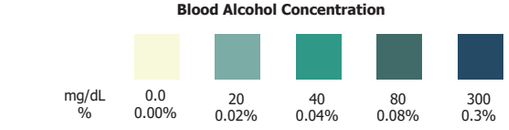
(4-2)

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:

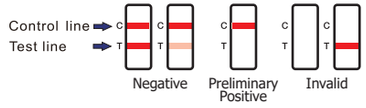
The test should be considered invalid if color only develops on the edge of the pad. The subject should be re-tested.

(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

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		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 Prime Screen® One Step 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
ß-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)		Hydromorphine	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
a-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		
Benzoylecgonine	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
Buspirone	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 Prime Screen® One Step 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
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
Hydrocortisone
O-Hydroxyhippuric Acid
p-Hydroxytyramine
Ibuprofen
Iproniazid
Isoproterenol
Isoxsuprine
Ketamine
Triamterene
Trifluoperazine
Trimethoprim
D, L-Tryptophan
Tyramine
Uric Acid
Verapamil
Zomepirac

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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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