

One Step Multi-Line Screen Test Device (Oral Fluid) Package Insert

A rapid, screening test for the simultaneous, qualitative detection of multiple drugs and metabolites in human oral fluid.

For medical and other professional *in vitro* diagnostic use only.

INTENDED USE & SUMMARY

The Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Cocaine, Marijuana, Methamphetamine, Opiate, and Phencyclidine and their metabolites in oral fluid at the following cut-off concentrations. The detection window, when drugs can be detected in oral fluid specimens using this test, is also indicated.

Test	Calibrator	Cut-off (ng/mL)	Detection Time
Amphetamine (AMP)	D-Amphetamine	50	10 min - 72 hrs
Cocaine (COC)	Benzoyllecgonine	20	10 min - 24 hrs
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	12	Up to 14 hrs
Methamphetamine (MET)	D-Methamphetamine	50	10 min - 72 hrs
Opiate (OPI)	Morphine	40	1 hr - several days*
Methadone (MTD)	Methadone	30	Up to 2 days
Phencyclidine (PCP)	Phencyclidine	10	/

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.¹

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.²

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.¹

OPI: The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates control pain by depressing the CNS, and demonstrate addictive properties when used for sustained periods of time. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation.³

*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.

MTD: Methadone is an analgesic compound most frequently used for the treatment of opiate addiction. One clinical study suggested that the ratio of methadone to plasma was approximately 0.51.⁵ Using known half life data for plasma, the detection window in saliva is expected to be up to 2 days after use.

PCP: Phencyclidine is a hallucinogen and, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity.⁴

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

PRINCIPLE

The Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen

will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

Each test line in the test device contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- All specimens should be considered potentially biohazardous and handled in the same manner as an infectious agent.
- The used collector and device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used if specimen cannot be collected at any time of the day may be used. If specimen cannot be tested immediately, it is recommended that specimen be stored at 2-8°C or -20°C for up to 72 hours. Specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimen using ice packs (2-8°C).

MATERIALS

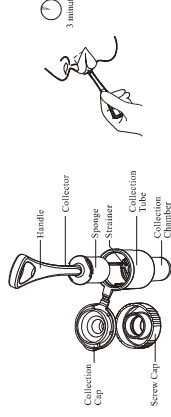
Materials Provided

- Test devices
- Security seals
- Materials Required But Not Provided
- Timer
- Collectors
- Package insert

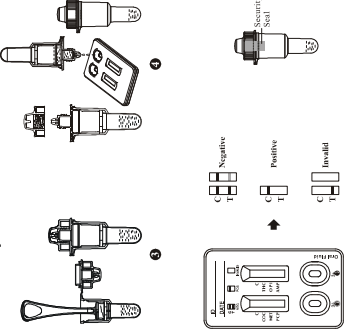
DIRECTIONS FOR USE

Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, tobacco products for at least 10 minutes prior to collection.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- Remove the collector from the sealed pouch and insert the sponge end of the collector into the mouth. Actively swab the inside of the mouth and tongue to collect oral fluid for a total of 3 minutes until the sponge becomes fully saturated. Gentle pressing of the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated. See illustration 1 and 2.
- Open the collection cap then remove the saturated oral fluid collector fully from the mouth and place into the collection chamber. Press sponge fully against the strainer to express as much oral fluid as possible into the collection chamber. Discard the collector. Snap the collection cap on the collection tube tightly. See illustration 3.
- Place the test device on a clean and level surface. Twist open the screw cap from the collection tube; invert the collection tube and transfer 3 drops of oral fluid (approximately 100 μ L) into each specimen well of the test device, and start the timer. Replace screw cap on the collection tube. Avoid trapping air bubbles in the specimen well. See illustration 4.
 - *Note: When opening the screw cap, do not open the collection cap attached to the collection chamber.
- Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.



6. Secure collection tube with security seal and send to laboratory for confirmation if necessary.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: *A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) 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) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is the preferred confirmatory method.
- 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 cut-off level of the test.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of \pm 50% cut-off and \pm 25% cut-off and tested with the Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid). The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP	COC	THC	MET	OPI	MTD	PCP
0% Cut-off	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0
-25% Cut-off	30	26	4	30	6	28	2	26
Cut-off	30	19	11	20	15	23	7	20
+25% Cut-off	30	7	23	6	24	11	19	7
+50% Cut-off	30	0	30	0	30	0	30	0

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) identified positive results at 10 minutes.

D-Amphetamine	50
AMPHETAMINE (AMP)	400
(1R,2S) (-) Ephedrine	400
OPIATE (OPI)	400

DL-Amphetamine	125	Morphine	40
l-Phenylethylamine	4,000	Cocaine	10
Triptamine	1,500	Ethylmorphine	24
D-Hydroxymphetamine	800	Hydromorphone	100
(+)-3,4-Methylenedioxymphetamine (MDA)	150	Hydrocodone	100
L-Amphetamine	4,000	Verapamil	400
COCaine (COC)		Oxycodone	25,000
Benzoyllecgonine	20	Morphine 3 β -D-Glucuronide	50
Cocaine HCl	20	Norcocaine	1,500
Cocacethylene	25	Normorphine	12,500
Egonine HCl	1,500	Nalorphine	10,000
Egonine methyl ester	12,500	Oxymorphone	25,000
MARIJUANA (THC)		Thebaine	1,500
11-nor- Δ^9 -THC-9 COOH	12	Diacetylmorphine	
11-nor- Δ^9 -THC-9 COOH	2	(Heroin)	50
Δ^9 -THC	6,000	6-Monoacetylmorphine	25
Δ^8 -THC	10,000	Bilirubin	3,500
METHAMPHETAMINE (MET)		Methadone (MTD)	
D-Methamphetamine	50	Methadone	30
Fenfluramine	60,000	Doxylamine	50,000
D-Hydroxymphetamine	400	Estrone-3 Sulfate	50,000
Methoxyphenamine	25,000	Phencyclidine	50,000
3,4-Methylenedioxymphetamine	50	PHENCYCLIDINE (PCP)	
(MDMA)		Phencyclidine	10
L-Phenylephrine	4,000	Tetrahydrozoline	50,000
Procaine	2,000		

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Multi-Drug One Step Multi-Line Screen Test Device (Oral Fluid) when tested at concentrations up to 100 μ g/mL.

Non Cross-Reacting Compounds

MDEA	Acetaminophen	Diazepam	Mefenemine	Promethazine
Acetophenetidine	Diclofenac	Dicyclanil	Meperidine	DL-Propriolol
N-Acetylprocainamide	Dicyclanil	Dicyclanil	Meprobamate	D-Propoxyphene
Acetylsalicylic acid	Diflunisal	Digoxin	Methamphetamine	D-Pseudoephedrine
Amoxycillin	Diphenhydramine	Diphenhydramine	Nalidixic acid	Quinine
Ampicillin	β -Estradiol	β -Estradiol	Naloxone	Quinine
Amitypyline	Ethyl-p-aminobenzoate	Ethyl-p-aminobenzoate	Naloxone	Ranitidine
Amobarbital	Cannabidiol	Cannabidiol	Salicylic acid	Salicylic acid
Ascorbic acid	L-Ephedrine	L-Ephedrine	Secobarbital	Secobarbital
Aspartame	Erythromycin	Erythromycin	Sulfamethazine	Sulfamethazine
Atropine	Fenpropafen	Fenpropafen	Sulindac	Sulindac
Benzoin acid	Furosemide	Furosemide	Temazepam	Temazepam
Benzoinamide	Genistein acid	Genistein acid	Tetracycline	Tetracycline
Benzphetamine	Hemoglobin	Hemoglobin	Tetrahydrocortisone 3-acetate	Tetrahydrocortisone 3-acetate
Bursatone	Hydrochlorothiazide	Hydrochlorothiazide	Tetrahydrocortisone 3, (D-glucuronide)	Tetrahydrocortisone 3, (D-glucuronide)
Caffeine	Hydrocortisone	Hydrocortisone	Theophylline	Theophylline
Chlorazepoxide	O-Hydroxyhippuric acid	O-Hydroxyhippuric acid	Thiamine	Thiamine
Chorallythrate	5-Hydroxytryptophane	5-Hydroxytryptophane	Thecladazine	Thecladazine
Chlorazepoxide	(serotonin)	(serotonin)	Penicillin-G	Penicillin-G
Chlorothalidate	3-Hydroxyxyramine	3-Hydroxyxyramine	Penicillin-G	Penicillin-G
DL-Chlorophthalazine	Isuproten	Isuproten	Perphenazine	Perphenazine
Chlorpromazine	Imipramine	Imipramine	Phenazone	Phenazone
Chlorzoxazone	Iproniazid	Iproniazid	Trans-2-phenylcyclopropylamine	Trans-2-phenylcyclopropylamine
Clonidine	(-)-Isoproterenol	(-)-Isoproterenol	Phentemine	Phentemine
Cortisone	Ketamine	Ketamine	Phenylpropanolamine	Phenylpropanolamine
Creatinine	Levamisole	Levamisole	Phenibutol	Phenibutol
Clomipramine	Loperamide	Loperamide	Prednisolone	Prednisolone
Deoxytocosterone	Maprotiline	Maprotiline	Prednisone	Prednisone
Dextromethorphan			Promazine	Promazine

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