Oral Fluid Drug Test Cylinder Package Insert

Package insert for testing of the following drugs:
Amphetamine, Benzodiazepine, Cocaine, Marijuana, Methamphetamine, Opiate and Oxycodone.

INTENDED USE & SUMMARY

The Oral Fluid Drug Test Cylinder is intended for screening for the presence of drugs and their metabolites in oral fluid. For professional *in vitro* diagnostic use only.

The Oral Fluid Drug Test Cylinder is a lateral flow chromatographic immunoassay for the qualitative detection of drugs and drug metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Benzodiazepine (BZO)	Oxazepam	10
Cocaine (COC)	Benzoylecgonine	50
Marijuana (THC)	Δ^9-THC	15
Methamphetamine (MET)	D-Methamphetamine	50
Opiates (OPI)	Morphine	50
Oxycodone (OXY)	Oxycodone	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.[1]

BZO: Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. Benzodiazepines are taken orally or by intramuscular or intravenous injection and are extensively oxidized in the liver to metabolites. Benzodiazepines can be detected in oral fluid after use.

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (*Erythroxylum coca*).[1]

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).[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 refer 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.

OXY: Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain. The approximate half- life in serum is averaged about 14 hours.

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. Liquid chromatography/mass spectrometry (LC/MS) and liquid chromatography/tandem mass spectrometry (LC/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 Oral Fluid Drug Test Cylinder 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 along the test strip 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 a 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 the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The Oral Fluid Drug Test Cylinder contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use it after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used collector and device should be discarded according to local regulations.
- Safety data sheets available for professional user upon request

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 with this test. Oral fluid collected at any time of the day may be used. If the specimen cannot be tested immediately, it is recommended that the specimen be stored at 2-8°C or -20°C for up to 72 hours. A specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimens using ice packs (2-8°C).

MATERIALS

Materials Provided

- Test cylinder
- Saliva collector
- Procedure card
- Security seal labels
- Package insert

Materials Required but Not Provided

- Timer
- Gloves

DIRECTIONS FOR USE

Allow the test device, specimen, and/or controls to reach room temperature (15-30ºC) 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.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Remove the collection swab from packaging. Start Timer. Relax the mouth and insert the collection swab into the mouth. The collection swab must be horizontal throughout the collection process. Using a circular motion, gently swab both cheeks 5-10 times, gums 5-10 times, and surface of tongue 5-10 times, actively swab the inside the mouth, top of tongue, and between cheek and gum. Collect oral fluid for **at least 3 minutes** until sponge is soft and fully saturated. No hard spots should be felt on the sponge when saturated, continue to collect the sample if a hard spot is present.

   Important: Do not bite, suck or chew on the collection swab. It is critical that the collection swab is held horizontally during collection, otherwise there will be insufficient saliva collected. During collection of the oral fluid, relax the mouth while swabbing the tongue and check as this will aid in the collection of the oral fluid. (See illustration 1)
3. Remove test device from sealed pouch and place upright on a clean, flat surface. Gently and slowly insert the collection swab into the test device, sponge first, until it reaches the bottom of the test device, then press until the collector cap sealed with the device tightly. (See illustration 2)

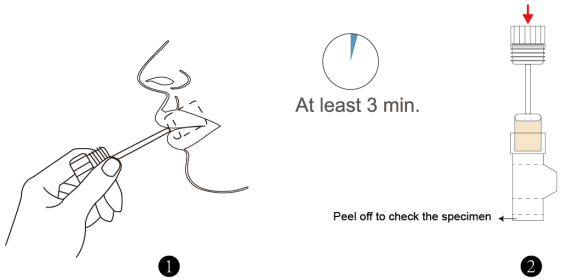
   Important: Keep test device upright while inserting collection swab. Once the collection swab is locked in place, the test device is airtight, tamper evident and ready to be shipped to a lab for confirmation if required. Alternatively, the test device can be disposed of.
4. Keep test device upright on a flat surface until the test is complete. Start timer. **Important:** If any test strips do not develop (invalid), peel away bottom of device label to inspect specimen volume. Refer to Notes and Troubleshooting.
5. Interpret results at 10 minutes.

Notes and Troubleshooting

Invalid results may occur, if the strips do not wick, peel off the label at the bottom of the device as marked to check if either there is enough specimen, or the oral fluid is too thick or viscous to run.

a.) If strips do not appear to flow when there is enough oral fluid, or the oral fluid is too thick to run move the device back and forth several times across a flat, clean surface. Ensure the device remains upright. Do not tilt the device when the test is running before reading results.

b.) Oral fluid tends to form air bubbles which sit at the bottom of the strip and prevent the strip from running. Gently tap the device on the table or counter surface popping the air bubble allowing capillary action to begin, thus initiating the test.



Interpretation results:

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

1. The Oral Fluid Drug Test Cylinder provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
3. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
4. 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.
5. The test does not distinguish between drugs of abuse and certain medications.
6. A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

100 clinical spiked saliva specimens were tested by the Oral Fluid Drug Test Cylinder comparing with the commercial oral fluid kit from Marketing. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP	BZO	COC	THC	MET	OPI	OXY
Positive	100%	100%	100%	100%	100%	100%	100%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	>99%	>99%	>99%	>99%	>99%	>99%	>99%

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and tested with the Oral Fluid Drug Test Cylinder. The results are summarized below.

Drug Conc. (Cut-off range)	AMP		BZO		COC		THC		MET		OPI		OXY	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	1	29	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Oral Fluid Drug Test Cylinder identified positive results at 10 minutes.

AMPHETAMINE (AMP)	
d- Amphetamine	50
Phentermine	120,000
R(-)-Amphetamine	10,000
(±)-Amphetamine	50
Serotonin	500,000
Octopamine	60,000
(±)-Phenylpropanolamine hydrochloride	100,000
Tryptamine	1,500
BENZODIAZEPINES (BZO)	
Oxazepam	10
Alprazolam	6
Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
Flunitrazepam	100
α-Hydroxyalprazolam	200
(±)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25
COCAINE (COC)	
Benzoylecgonine	50
Cocaine	50
Cocaethylene	60
Ecgonine	2,500
Ecgonine methyl ester	25,000
N-Acetylprocainamide	25,000
Norcocaine	1,250
MARIJUANA (THC)	
Δ^9-Tetrahydrocannabinol	15
METHAMPHETAMINE (MET)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)- (-) Ephedrine	400
1-Ephedrine	400
Mephentermine	800
(-) Deoxyephedrine, L-Methamphetamine	3,000
Ephedrine	800
4-Methylethcathinone hydrochloride	25,000
Ethylone hydrochloride	25,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	100
(+/-)-Methylenedioxyamphetamine (MDA)	25,000
D,L-Methamphetamine	4,000
(±)-Amphetamine	10,000
Acetylsalicylic	4,000
Chlorothiazide	25,000
R(-)-Methamphetamine	400
OPIATE (OPI)	
Morphine	50
Codeine	10
Ethylmorphine	24
Hydromorphine	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-d-glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	15
Bilirubin	3,500
OXYCODONE (OXY)	
Oxycodone	40
Hydrocodone	12,500
Levorphanol	25,000
Naloxone	25,000
Naltrexone	50,000
Secorbarbital	100,000
Oxymorphone	200
Hydromorphone	50,000

Interference Compounds

A study was conducted to determine the interference compounds of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Oral Fluid Drug Test Cylinder when tested at concentrations up to 100 μg/mL.

Non-interfering Compounds Tables

Acetaminophen	Diclofenac	Loperamide	d-Pseudoephedrine
Acetophenetidin	Dicyclomine	Meprobamate	Quinacrine
Acetylsalicylic acid	Diflunisal	Methylphenidate	Quinine
Aminopyrine	Digoxin	Nalidixic acid	Quindine
Amoxicillin	Diphenhydramine	Naproxen	Ranitidine
Ampicillin	β-Estradiol	Niacinamide	Salicylic acid
Amitriptyline	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Ascorbic acid	l-Epinephrine	Nimesulide	Sulindac
Apomorphine	Erythromycin	Norethindrone	Tetracycline
Aspartame	Fenoprofen	Noscapine	Tetrahydrocortisone
Atropine	Furosemide	d,l-Octopamine	3-acetate
Benzilic acid	Gentisic acid	Oxalic acid	Tetrahydrocortisone
Benzoic acid	Hemoglobin	Oxolinic acid	3 (β-d-glucuronide)
Benzphetamine	Hydralazine	Oxymetazoline	Theophylline
Caffeine	Hydrochlorothiazide	Papaverine	Thiamine
Chloral hydrate	Hydrocortisone	Penicillin-G	Thioridazine
Chloramphenicol	o-Hydroxyhippuric acid	Pentazocine	d,l-Tyrosine
Chlorothiazide	βHydroxynorephedrine	Perphenazine	Tolbutamide
d,l-Chlorpheniramine	5-Hydroxytryptamine	Phenelzine	Trazodone
Chlorpromazine	(Serotonin)	Trans-2-phenylcyclo-	Triamterene
Chloroquine	3-Hydroxytyramine	propylamine	Trifluoperazine
Cholesterol	Ibuprofen	Phentermine	Trimethoprim
Clonidine	Iproniazid	Phenylpropanolamine	d,l-Tryptophan
Cortisone	(-) Isoproterenol	Prednisolone	Tyramine
Creatinine	Isoxsuprine	Phenolbarbital	Uric acid
Deoxycorticosterone	Ketoprofen	Prednisone	Verapamil
Dextromethorphan	Labetalol	d,l-Propranolol	Zomepirac

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