

# Accurate LaneWorkSafe

## Oral Fluid Drug Screen Device (6)

### From LaneWorkSafe

Package Insert for the AMP/mAMP/COC/OPI/THC/BZO  
Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana and Benzodiazepines in human oral fluid.

### For Professional Use.

#### INTENDED USE

The **Accurate Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/BZO is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana and Benzodiazepines, in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylcegonine	50 ng/mL
Opiates (OPI)	Morphine	50 ng/mL
Marijuana (THC)	$\Delta^9$ -THC	25 ng/mL
Benzodiazepines (BZO)	Oxazepam	50 ng/mL

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.

#### SUMMARY AND EXPLANATION OF THE TEST

**Accurate Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/BZO is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

#### AMPHETAMINE (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, Amphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use<sup>1</sup>.

The Amphetamine assay contained within the **Accurate Oral Fluid Drug Screen Device** yields a positive result when the Amphetamine concentration in oral fluid exceeds 50 ng/mL.

#### METHAMPHETAMINE (mAMP)

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. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use<sup>1</sup>.

The Methamphetamine assay contained within the **Accurate Oral Fluid Drug Screen Device** yields a positive result when the Methamphetamine concentration in oral fluid exceeds 50 ng/mL.

#### COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (*Erythroxylum coca*). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine, benzoylcegonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use<sup>1</sup>. Cocaine and benzoylcegonine can be detected in oral fluids for up to 24 hours after use<sup>1</sup>.

The Cocaine assay contained within the **Accurate Oral Fluid Drug Screen Device** yields a positive result when the cocaine in oral fluid exceeds 50 ng/mL.

#### OPIATE (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 act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. 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. Using an immunoassay cutoff level of 50 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose<sup>2</sup>. 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a product of heroin. Morphine is the major product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose.

The Opiates assay contained within the **Accurate Oral Fluid Drug Screen Device** yields a positive result when the concentration of Morphine in oral fluid exceeds the 50 ng/mL cut-off level.

#### MARIJUANA (THC)

Tetrahydrocannabinol, the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in saliva 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<sup>3</sup>. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use<sup>3</sup>.

#### BENZODIAZEPINES (BZO)

Benzodiazepines are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolised in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines.

The Benzodiazepines assay contained within the **Oral Fluid Drug Screen Device** yields a positive result when the Oxazepam concentration in oral fluid exceeds 50 ng/mL.

#### PRINCIPLE

The **Accurate Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/BZO 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 coloured 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 coloured line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a coloured 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 coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### PRECAUTIONS

- For Professional use.
- Do not use after the expiration date.
- The Oral Fluid Drug Screen Device should remain in the sealed pouch until use.
- The test device is for single use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

#### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices 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 assay. Oral fluid collected at any time of the day may be used.

#### MATERIALS

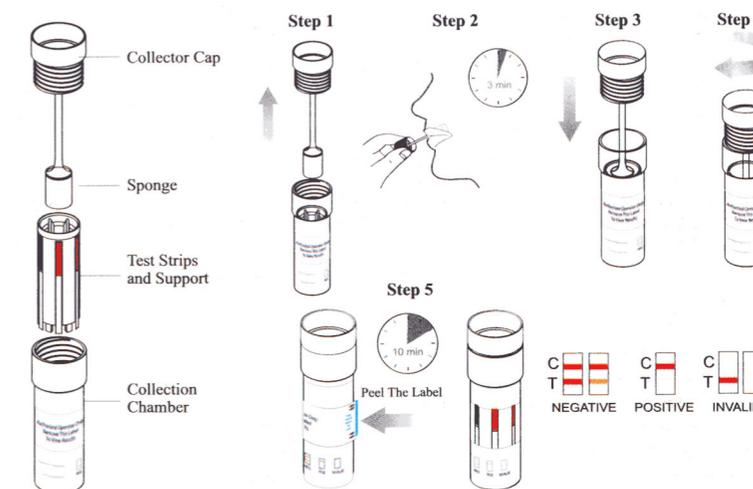
Materials Provided  
• Test devices • Package insert • Procedure card

Materials Required But Not Provided  
• Timer

#### DIRECTIONS FOR USE

**Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.**

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it as soon as possible.
2. Remove the test device from the sealed pouch and screw the Collector Cap counterclockwise to pull out the whole piece of collection stick with Sponge from the Collection Chamber. (Step 1)
3. Insert the sponge end of the collection stick into the mouth. Close mouth and gently chew the sponge for saliva excretion. Soak sponge into saliva in mouth and swab the inside of the mouth and tongue **to collect oral fluid for a total of 3 minutes** until the sponge becomes completely soft and fully saturated with saliva. No hard spots should be felt on the sponge when saturated. (Step 2)
4. Remove the sponge from the mouth. With gentle pressure, place the collection stick with saturated sponge into Collection Chamber. (Step 3)
5. Screw the Collector Cap clockwise to secure the cap and start the timer. (Step 4)
6. Mark donor ID on the test device. Peel off the label to read test results. Wait for the colour line(s) to appear on the test strips. **Read results at 10 minutes.** Do not read results after 1 hour. (Step 5)
7. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.



## INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

### NEGATIVE:

Two lines appear. \* One colour line should be in the control region (C), and another apparent colour line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

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

### POSITIVE:

One colour line appears in the control region (C). No line appears in the test region (T).

This positive result indicates that the drug concentration is above the detectable level.

### INVALID:

Control line 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 supplier.

## QUALITY CONTROL

A procedural control is included in the test. A colour 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.

## LIMITATIONS

1. The **Accurate Oral Fluid Drug Screen Device** 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 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.

4. The test has been developed for testing saliva samples only. No other fluids have been evaluated. Do NOT use this device to test anything but saliva.

## 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 **Accurate Oral Fluid Drug Screen Device**. The results are summarised below.

Drug concentration Cut-off Range	n	AMP		mAMP		COC		OPI		THC		BZO	
		-	+	-	+	-	+	-	+	-	+	-	+
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	29	1	30	0	27	3	27	3	28	2
Cut-off	30	13	17	16	14	19	11	18	12	14	16	13	17
+25% Cut-off	30	4	26	7	23	5	25	3	27	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the **Accurate Oral Fluid Drug Screen Device** for AMP/mAMP/COC/OPI/THC/BZO identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/ml)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
$\beta$ -Phenylethylamine	4,000
( $\pm$ )-3,4-Methylenedioxyamphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
Tyramine	1,000

METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S) - (-) Ephedrine	400
Fenfluramine	60,000
Methoxyphenamine	25,000
( $\pm$ )-3,4-Methylenedioxymethamphetamine (MDMA)	50
p-Hydroxymethamphetamine	400
L-Phenylephrine	4,000
Procaine	2,000

COCAINE (COC)	
Benzoylecgonine	50
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine methyl ester	12,500

OPIATES (OPI)	
Morphine	50
Bilirubin	3,500
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphone	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3- $\beta$ -D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500

MARIJUANA (THC)	
$\Delta^8$ -THC	25
$\Delta^9$ -THC	25

BENZODIAZEPINES (BZO)	
$\alpha$ -Hydroxylprazolam	1,260
Alprazolam	40
Bromazepam	400
Chlordiazepoxide	780
Chlordiazepoxide HCl	390
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
( $\pm$ ) Lorazepam	1,560
RS-Lorazepam glucuronide	160

Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	50
Temazepam	20
Triazolam	2,500

## 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 **Accurate Oral Fluid Drug Screen Device** when tested with concentrations up to 100  $\mu$ g/mL.

Acetaminophen	Furosemide	Prednisolone
Acetophenetidin	Gentisic acid	Prednisone
N-Acetylprocainamide	Hemoglobin	D/L-Propranolol
Acetylsalicylic acid	Hydralazine	D-Propoxyphene
Aminopyrine	Hydrochlorothiazide	D-Pseudoephedrine
Amoxicillin	Hydrocortisone	Quinacrine
Ampicillin	O-Hydroxyhippuric acid	Quinine
L-Ascorbic acid	p-Hydroxytyramine	Quindine
Apomorphine	Ibuprofen	Ranitidine
Aspartame	Iproniazid	Salicylic acid
Atropine	D/L -Isoproterenol	Serotonin
Benzphetamine	Isoxsuprine	Sulfamethazine
D/L-Brompheniramine	Ketamine	Sulindac
Caffeine	Ketoprofen	Tetracycline
Cannabidol	Labetalol	Tetrahydrocortisone 3-acetate
Chloral hydrate	Loperamide	Tetrahydrocortisone 3 ( $\beta$ -D-glucuronide)
Chloramphenicol	Meperidine	Thiamine
Chlorothiazide	Meprobamate	Thioridazine
D/L-Chloropheniramine	Methylphenidate	D/L-Tyrosine
Chlorpromazine	Nalidixic acid	Tolbutamide
Chloroquine	Naloxone	Triamterene
Cholesterol	Naltrexone	Trifluoperazine
Clonidine	Naproxen	Trimethoprim
Cortisone	Niacinamide	D/L-Tryptophan
L-Cotinine	NifedipineBenzoic acid	Uric acid
Creatinine	Norethindrone	Verapamil
Deoxycorticosterone	D-Norpropoxyphene	Zomepirac
Dextromethorphan	Noscapine	
Diclofenac	D/L-Octopamine	
Diflunisal	Oxalic acid	
Digoxin	Oxolinic acid	
Diphenhydramine	Oxymetazoline	
L-Y-Ephedrine	Papaverine	
$\beta$ -Estradiol	Penicillin-G	
Estrone-3-sulfate	Pentazocine hydrochloride	
Ethyl-p-aminobenzoate	Perphenazine	
L(-)-Epinephrine	Phenelzine	
Erythromycin	Trans-2-phenylcyclopropylamine hydrochloride	
Fenoprofen	Phenylpropanolamine	

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