Accurate

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Oral Fluid Drug Screen Device (7) From LaneWorkSafe

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

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

For Professional Use.

INTENDED USE

The ***Accurate Oral Fluid Drug Screen Device*** for AMP/mAMP/COC/OPI/THC/BZO/OXY is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Benzodiazepines and Oxycodone, 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)	Cocaine	50 ng/mL
Opiates (OPI)	Morphine	50 ng/mL
Marijuana (THC)	Δ^9-THC PARENT	30 ng/mL
Benzodiazepines (BZO)	Oxazepam	50 ng/mL
Oxycodone (OXY)	Oxycodone	40 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 chromatographyltandem 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/OXY is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilises 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 selfadministered 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[1].

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'.

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, benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].

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.

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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[2]. 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[3]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[3].

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.

OXYCODONE (OXY)

Oxycodone is a powerful analgesic that can produce dependence and tolerance after prolonged use.

Oxycodone is a semisynthetic opioid derived from thebaine (a natural constituent in poppy seeds) and is frequently prescribed for post operative pain management. Oxycodone is available in Australia on prescription in various formulations, including Endone® (rapid absorption), Oxycontin® (extended release) and Targin® (a combination of oxycodone and naloxone).

The Oxycodone assay contained within the Oral Fluid Drug Screen Device yields a positive result when the Oxycodone concentration in oral fluid exceeds 40 ng/ml.

PRINCIPLE

The ***Accurate Oral Fluid Drug Screen Device*** for AMP/mAMP/COC/OPI/THC/BZO/OXY 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
• Individually packed screening devices • Oral fluid collection swabs • Package insert

Materials Required But Not Provided
• Timer

DIRECTIONS FOR USE

Bring tests to room temperature (15-30°C) before removing from foil pouch prior to testing. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

• The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay.

• 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.

• Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.

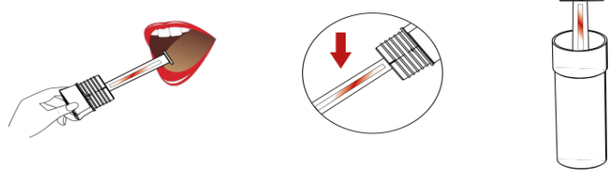
• Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, and tongue) several times, and then hold swab in mouth until colour on the saturation indicator strip appears in the indicator window of collection swab. Important: Do not bite, suck, or chew on the sponge.

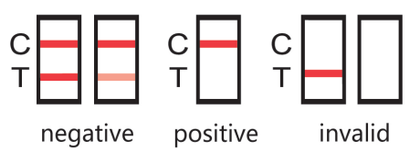
NOTE: After 7 minutes, proceed with the test below, even if colour on the saturation indicator has not appeared in the indicator window.

• Remove the collection swab from the mouth and insert it, sponge first, into the screening device. Push cap down until fully locked and air tight.

• Test device upright on flat surface and keep upright while test is running. Wait for the coloured bands to appear in test results area. Read results at 10 minutes. Do not interpret the result after 20 minutes.

• NOTE: Once the collection swab locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).





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 chromatographyltandem 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 ± 50% cut-off and ± 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 parent		BZO		OXY	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
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	30	0	30	0	29	1	28	2	30	0	30	0	28	2
Cut-off	30	12	18	13	17	12	18	10	20	10	20	14	16	10	20
+25% Cut-off	30	2	28	3	27	2	28	9	21	4	26	4	26	4	26
+50% Cut-off	30	0	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
L-Amphetamine	4,000
(±)-3,4-Methylenedioxyamphetamine (MDA)	150
Phentermine	40,000
PMA	125
Tyramine	3,000
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
Fenfluramine	3,000
L-Methoxyphenamine	500
L-Phenylephrine	2,500
MDEA	400
(±)-3,4-Methylenedioxymethamphetamine (MDMA)	75
Mephentermine	200
PMMA	50
Procaine	2,500
COCAINE (COC)	
Cocaine	50
Benzoylecogonine	500
Ecgonine	>100,000
Ecgonine methyl ester	50, 000
OPIATES (OPI)	
Morphine	50
Codeine	15
Diacetylmonphine (Heroin)	60
Ethylmorphine	30
Hydrocodone	60
Hydromorphine	125
6-Monoacetylmorphine (6-MAM)	60
Morphine 3-β-D-Glucuronide	60
Nalorphine	12,500
Oxycodone	31,250
Oxymorphone	31,250
Thebaine	6,250
MARIJUANA (THC)	
Δ^9 -Tetrahydrocannabinol	30
Δ^8 -Tetrahydrocannabinol	40
11-nor-Δ^9-THC-9 COOH	8
11-hydroxy-Δ^9 -THC	150
Cannabinol	1,000
Cannabidiol	>10,000
BENZODIAZEPINES (BZO)	
Oxacepam	50
Alprazolam	75
Bromazepam	40
Chlordiazepoxide	50
Clonazepam	200
Clorazepate	100
Clbazam	30
Diazepam	75
Estazolam	50
Desalkyflurazepam	40
Flunitrazepam	50
Flurazepam	50
Lorazepam	100
Medazepam	50
Nitrazepam	50
Nordiazepam	30
Prazepam	100
Temazepam	40
Triazola	75
OXYCODONE (OXY)	
Oxycodone	40
Hydrocodone	1,000
Hydromorphone	6,250
Naloxone	6,250
Oxymorphone	40

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 Oral Screen Saliva Drug Test when tested at concentrations up to 100 μg/ml.

(-)-Ephedrine (Except MET)
(+)-Naproxen
(+/-)-Ephedrine (Except MET)
4-Dimethyllaminoantiyrine
Acetaminophen (Except ACE)
Acetone
Albumin
Amitriptyline (Except TCA)
Ampicillin
Aspartame
Aspirin
Benzocaine
Bilirubin
b-Phenylethyl-amine
Caffeine
Chloroquine
Chlorpheniramine
Creatine
Dextromethorphan
Dextrorphan tartrate
Dopamine
Erythromycin
Ethanol
Furosemide
Glucose
Guaiacol Glyceryl Ether
Hemoglobin
Ibuprofen
Imipramine (Except TCA)
Isoproterenol
Lidocaine
Methadone (Except MTD)
Oxalic Acid
Penicillin-G
Pheniramine
Phenothiazine
Procaine
Protonix
Pseudoephedrine
Quinidine
Ranitidine
Sertraline
Tyramine
Vitamin C (Ascorbic Acid)
Trimeprazine
Venlafaxine

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