



Clonal Oral Fluid DoA Screening Device

Clonal Technologies

Oral Fluid Drug Screen Device

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

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, THC, Opiates and their metabolites in human oral fluids. For Professional and In Vitro Diagnostic Use Only.

INTENDED USE

The "Oral Fluid Drug Screen Device" for AMP/MAMP/COC/OP/THC is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off Value
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)	11-nor- Δ^9 THC-9 COOH	25 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 (GS/MS) and gas chromatography/tandem mass spectrometry (GS/MS/MS) are the preferred confirmatory methods. Professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF THE TEST

The Oral Fluid Drug Screen Device for AMP/MAMP/COC/OPI/THC and their metabolites 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 5-10minutes and up to 72 hours after use.

The Amphetamine assay contained within the 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 5-10minutes and up to 72 hours after use.

The Methamphetamine assay contained within the Oral Fluid Drug 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-administration by nasal inhalation, intravenous injection and free-base smoking, depending on the route of administration, Cocaine can be detected in oral fluid as early as 5-10minutes following use. Cocaine and benzoylcegonine can be detected in oral fluids for up to 24 hours after use.

The cocaine assay contained within the Oral Fluid Drug Screen Device yields a positive result when the cocaine metabolite 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 them intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 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. 6-monoacetylmorphine (6-MAN) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is the major metabolic product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose.

The Opiates assay contained within the Oral Fluid Drug Screen Device yields a positive result when the concentration of Morphine in oral fluid exceeds the 50 ng/ml cutoff 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. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use.

The Marijuana assay contained within the Oral Fluid Drug Screen Device yields a positive result when the concentration of THC in oral fluid exceeds the 25 ng/ml cutoff level.

PRINCIPLE

The Oral Fluid Drug Screen Device for AMP/MAMP/COC/OPI/THC is an immunoassay based on the principle of competitive binding. Drugs that are 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 cutoff 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 cutoff 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

REAGENTS

The test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Morphine and 11-nor- Δ^9 THC-9 COOH.

PRECAUTIONS

- For Professional use only
- Do not use after the expiration date.
- The Oral Fluid Drug Screen Device should remain in the sealed pouch until 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 can be used.

MATERIALS

Materials Provided

- Test devices

Materials Required But Not Provided

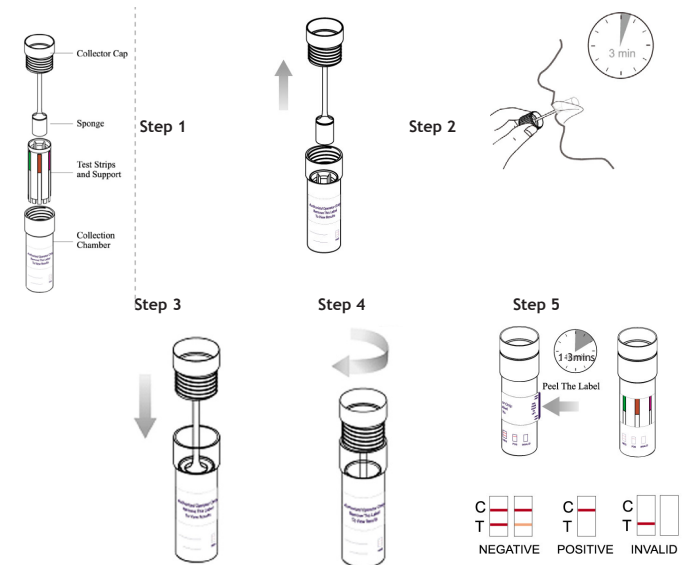
- Timer

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 10minutes prior to collection of oral fluid specimen.

- Remove the test from the sealed pouch and use it as soon as possible.
- 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 3minutes until the sponge becomes completely soft and fully saturated with saliva. No hard spots should be felt on the sponge when saturated.

- Remove the sponge from the mouth. With gentle pressure, place the collection stick with saturated sponge into Collection Chamber,
- Screw the Collector Cap clockwise to secure the cap and start the timer.
- Place device upright on hard-surface. Do not tip. Peel off the label to read test results. Wait for the colour line(s) to appear on the test strips. Read results between 1-3minutes. Do not read results after 1 hour. Mark patient ID on the device.
- 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 whether 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 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 (GS/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.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A Phosphate-buffered saline(PBS) pool was spiked with drugs to target concentration of ±50% cut-off and ±25% cut-off and tested with the Oral fluid Drug Screen Device. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		MAMP		COC		OPI		THC	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	29	1	30	0	27	3	25	5
Cut-off	30	13	17	16	14	19	11	18	12	15	15
+25% Cut-off	30	4	26	7	23	5	25	3	27	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Analytical Sensitivity

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

Drug	Concentration (ng/ml)
Amphetamine (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
β-Phenylethylamine	4,000
(+)-3,4-Methylenedioxymphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S)- (-) Ephedrine	400
Fenfluramine	60,000
Methoxyphenamine	25,000
3,4-Methylenedioxymphetamine(MDMA)	50
p-Hydroxymethamphetamine	400
L-Phenylephrine	4,000
Procaine	2,000
COCAINE(COC)	
Benzoylcegonine	20
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine methyl ester	12,500

OPIATES(OPI)	
Morphine	40
Bilirubin	3,500
Codeine	10
Diacetylmorphine(Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Levorphanol	100
6-Monoacetylmorphine	400
Morphine 3-β-D-Glucuronide	25
Nalorphine	50
Normorphine	10,000
Norcodeine	12,500
Oxycodone	1,500
Oxymorphone	25,000
Thebaine	1,500
MARIJUANA(THC)	
11-nor-Δ ⁹ THC-9 COOH	12
Cannabinol	12,500
11-nor-Δ ⁸ THC-9 COOH	2
Δ ⁸ -THC	6,000
Δ ⁹ -THC	10,000
PHENCYCLIDINE(PCP)	
Phencylidine	10
Tetrahydrozoline	50,000

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 Oral Fluid Drug Screen Device when tested with concentrations up to 100ng/ml.

Acetaminophen	Benzoic acid
Acetophenetidin	Benzphetamine
N-Acetylprocainamide	D/L-Brompheniramine
Acetylsalicylic acid	Caffeine
Aminopyrine	Cannabidol
Amoxicillin	Chloralhydrate
Ampicillin	Chloramphenicol
L-Ascorbic acid	Chlorothiazide
Apomorphine	D/L-Chloropheniramine
Aspartame	Chlorpromazine
Atropine	Chloroquine
Cholesterol	Norethindrone
Clonidine	D-Norproprxyphene
Cortisone	Noscapine
L-Cotinine	D/L-Octopamine
Creatinine	Oxalic acid
Deoxycorticosterone	Oxolinic acid
Dextromethorphan	Oxymetazoline
Diclofenac	Papaverine
Diflunisal	Penicillin-G

Digoxin	Pentazocine hydrochloride
Diphenhydramine	Perphenazine
L-ψ-Ephedrine	Phenelzine
β-Estradiol	Trans-2-phenylcyclopropylamine hydrochloride
Estrone-3-sulfate	Phenylpropanolamine
Ethyl-p-aminobenzoate	Prednisolone
L(-)-EPINEPHRINE	Prednisone
Erythromycin	D/L-Propranolol
Fenoprofen	D-Propoxyphene
Furosemide	D-Pseudoephedrine
Gentisic acid	Quinacrine
Hemoglobin	Quinine
Hydralazine	Quindine
Hydrochlorothiazide	Rnitidine
Hydrocortisone	Salicylic acid
O-Hydroxyhippuric acid	Serotonin
p-Hydroxytyramine	Sulfamethazine
Ibuprofen	Sulindac
Iproniazid	Tetracycline
D/L-Isoproterenol	Tetrahydrocortisone 3-acetate
Isoxsuprine	Tetrahydrocortisone 3(β-D-glucuronide)
Ketamine	Thiamine
Ketoprofen	Thioridazine
Labetalol	D/L-Tyrosine
Lopemoramide	Tolbutamide
Meperidine	Triamterene
Meprobamate	Trifluoperazine
Methylphenidate	Trimethoprim
Nalidixic acid	D/L-Tryptophan
Naloxone	Tyramine
Naltrexone	Uric acid
Naproxen	Verapamil
Niacinamide	Zomepirac
Nifedipine	

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