Opiates (OPI)

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, shivering, nausea and irritability. Opiates can be taken orally or by injection routes including, intramuscular and subcutaneous; intranasal routes may also take the drug 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 2-72 hours after the dose. 8-Monoacetylmorphine (8-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and can be detectable for 24-96 hours following an opiate dose.

The Opiates assay contained within the OrAlert™ Oral Fluid Drug Screen Device yields a positive result when the morphine concentration in oral fluid exceeds 40 ng/mL.

Marijuana (THC)

Tetrahydrocannabinol (THC), the active ingredient in the marijuana plant (cannabis sativa), is detectable in oral fluid shortly after use. During the detection of the drug it is found to be directly by the eventual exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity. 9-History studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.

The THC assay contained within the OrAlert™ Oral Fluid Drug Screen Device yields a positive result when the ∆9-THC concentration in oral fluid exceeds 100 ng/mL.

Phencyclidine (PCP)

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired sample and oral fluid can be done the same day for consistency. PCP was detected in the oral fluid of 79 patients at levels as low as 2 ng/mL, and as high as 600 ng/mL.

The Phencyclidine assay contained within the OrAlert™ Oral Fluid Drug Screen Device yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders.

The Benzodiazepines assay contained within the OrAlert™ Oral Fluid Drug Screen Device yields a positive result when the oxazepam concentration in oral fluid exceeds 10 ng/mL.

ASSAY PRINCIPLE

The OrAlert™ Oral Fluid Drug Screen Device for Amphetamine/mAMP or Methamphetamine is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, opioids, marijuana, phencyclidine, benzodiazepines and their metabolites in oral fluid. 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 following use. Amphetamine can be detected in oral fluid for up to 72 hours after use.

The Amphetamine assay contained within the OrAlert™ 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 that is chemically related to amphetamine but with greater central nervous system (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 5-10 minutes following use. Methamphetamine can be detected in oral fluid for up to 72 hours after use.

The Methamphetamine assay contained within the OrAlert™ 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 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 and its metabolites, benzoylecgonine and ecgonine methylster, can be detected in oral fluid as early as 5-10 minutes following use. Cocaine and benzoylecgonine can be detected in oral fluid up to 4-8 hours after use.

The Cocaine assay contained within the OrAlert™ Oral Fluid Drug Screen Device yields a positive result when the cocaine metabolite concentration in oral fluid exceeds 20 ng/mL.

For Forensic Use Only

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

The OrAlert™ Oral Fluid Drug Screen Device for Amphetamine/mAMP or Methamphetamine is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, opioids, marijuana, phencyclidine, benzodiazepines and their metabolites in oral fluid. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.
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 OrALert™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.

**METHAMPHETAMINE (mAMP)**

- **0% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **50% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **+50% Cut-off**
  - 0
  - 0
  - 0
  - 0

**PHENCYCLIDINE (PCP)**

- **0% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **50% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **+50% Cut-off**
  - 0
  - 0
  - 0
  - 0

**BENZODIAZEPINES (BZO)**

- **0% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **50% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **+50% Cut-off**
  - 0
  - 0
  - 0
  - 0

**OPIATES (OPI)**

- **0% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **50% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **+50% Cut-off**
  - 0
  - 0
  - 0
  - 0

**COCAINES (COC)**

- **0% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **50% Cut-off**
  - 0
  - 0
  - 0
  - 0

- **+50% Cut-off**
  - 0
  - 0
  - 0
  - 0

**PERFORMANCE CHARACTERISTICS**

A PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the OrALert™ Oral Fluid Drug Screen Device. The results are summarized below.

**BIBLIOGRAPHY**


**Negatives**

- d,l-Ephedrine 800
- Acetaminophen
- Deoxycorticosterone
- Loperamide
- Prednisone
- l-Ephedrine 400
- Acetophenetidin
- Dextromethorphan
- Meperidine
- d,l-Propranolol
- N-Acetylprocainamide
- Diclofenac
- Meprobamate
- d-Propoxyphene
- Fenfluramine 60,000
- Acetylsalicylic acid
- Diflunisal
- Methylphenidate
- d-Pseudoephedrine
- p-Hydroxymethamphetamine 400
- l-Cotinine
- Ketoprofen
- Prednisolone
- Verapamil
- Caffeine
- Hemoglobin
- Oxalic acid
- 3-acetate
- Cannabidiol
- Hydralazine
- Oxolinic acid
- Thiamine
- Chloral hydrate
- Hydrochlorothiazide
- Naproxen
- Ranitidine
- Apomorphine
- Erythromycin
- Niacinamide
- Salicylic acid
- Aspartame
- Δ9 –THC 100
- l-Methamphetamine 3,000
- Methoxyphenamine 25,000
- 11-nor-Δ9 –THC -9 COOH
- (+)-3,4-Methylenedioxyamphetamine (MDA) 150
- β-Phenylethylamine 4,000
- 5,5-Diphenylhydantoin 40,000
- β-Phenylethylamine 4,000
- (+)-3,4-Methylenedioxyamphetamine (MDA) 150
- 1. The OrALert™ 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) are 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 of level of detection.

**Benzodiazepines (BZO)**

- Oxazepam 10,000
- Alprazolam 15
- Diazepam 10
- Lorazepam 10
- Chloral hydrate 325
- Chlordiazepoxide 150
- Clonazepam 150
- Desmethyldiazepam 15
- Molindone 10
- Oxazepam 10
- S,S-Diphenylhydantoin 40,000
- Ethacridine 15
- Flurazepam 250
- Nortriptyline 15
- Phenobarbital 10
- Ethylmorphine 12
- Morphine 40,000
- Nitrazepam 250
- Nortriptyline 200
- Phencyclidine 15
- Methadone 1,200
- Methadone 1,200
- Ethylmorphine 12
- Methadone 1,200
- Methadone 1,200
- Ethylmorphine 12
- Methadone 1,200
- Ethylmorphine 12
- Methadone 1,200
- Ethylmorphine 12
- Methadone 1,200