# Oral Fluid Drug Test Cube
# Package Insert
## For Employment and Insurance Use.

Package insert for testing of the following drugs:

Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Codeine, Ecstasy, Marijuana, Methadone, Methamphetamine, Methaqualone, Morphine, Opiate, Oxycodone, Propoxyphene and Tricyclic Antidepressants,

## INTENDED USE & SUMMARY

The Oral Fluid Drug Test Cube is intended for screening for the presence of drugs and their metabolites in oral fluid.

The Oral Fluid Drug Test Cube is a lateral flow chromatographic immunoassay for the qualitative and simultaneous 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 |
| Barbiturate (BAR) | Secobarbital | 50/300 |
| Benzodiazepine (BZO) | Oxazepam | 10/50 |
| Buprenorphine (BUP) | Buprenorphine | 5/10 |
| Cocaine (COC) | Benzoylecgonine | 20 |
| Codeine (COD) | Codeine | 10 |
| Ecstasy (MDMA) | 3,4-Methylenedioxymethamphetamine | 50 |
| Marijuana (THC) | 11-nor-$\Delta^9$-THC-9 COOH | 12 |
| Marijuana (THC) | $\Delta^9$-THC | 25/50 |
| Methadone (MTD) | Methadone | 30/75 |
| Methamphetamine (MET) | d-Methamphetamine | 50 |
| Methaqualone (MQL) | Methaqualone | 100/150 |
| Opiates (OPI) | Morphine | 15 |
| Opiates (OPI) | Morphine | 40 |
| Oxycodone (OXY) | Oxycodone | 50/20 |
| Propoxyphene (PPX) | Propoxyphene | 50 |
| Tricyclic Antidepressants (TCA) | Nortriptyline | 100 |

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]

**BAR:** Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

**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. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. 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.

**BUP:** Buprenorphine is a semisynthetic opioid analgesic derived from Thebaine, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the “ceiling effect”, which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

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

**COD:** Codeine is an opiate used to treat pain, as a cough medicine, and for diarrhea. It is typically used to treat mild to moderate degrees of pain. Greater benefit may occur when combined with paracetamol (acetaminophen) or a nonsteroidal anti-inflammatory drug (NSAID) such as aspirin or ibuprofen. Evidence does not support its use for acute cough suppression in children or adults. In Europe it is not recommended as a cough medicine in those under twelve years of age. It is generally taken by mouth. It typically starts working after half an hour with maximum effect at two hours. The total duration of its effects last for about four to six hours.

**MDMA:** MDMA is an abbreviation for the chemical methylenedioxymethamphetamine MDMA. It has many street names including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. it is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or stoke. MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the parent drug of MDMA, and MDEA (methylenedioxyethyl MDMA), also known as EVE. They all share the MDMA-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100 mg; the threshold toxic dose is 500mg. The effects of MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours. it is detectible in the oral fluid for up to 3 days after use.

**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) and the subsequent sequestering of the drug in the buccal cavity.[2]

**MTD:** Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. In addition to use as a narcotic agonist, methadone is being used more frequently as a pain management agent. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Based on the oral fluid/plasma ratio calculated over oral fluid pH ranges of 6.4-7.6 for therapeutic or recreational doses of methadone, a cut-off <50 ng/mL is suggested. Due to this recommendation, the cut-off level of the methadone test was calibrated to 30 ng/mL.

**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]

**MQL:** Methaqualone is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956.It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form and is also available in Europe and other countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule.

**OPI (MOP):** 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.

**PPX:** Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene but shows a greater local anesthetic effect.

**TCA:** TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver.

**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 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 Cube 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 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 proper volume of specimen has been added and membrane wicking has occurred.

## REAGENTS

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

## PRECAUTIONS

- *For employment and insurance use.*
- Do not use 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.

## 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. Perform testing immediately after collection.

## MATERIALS

### Materials Provided

- Test cubes
- Oral Fluid collectors (with indicator)
- Security seal labels
- Package insert

### Materials Required But Not Provided

- Timer
- Gloves

## DIRECTIONS FOR USE

**Allow the test device, and/or controls to reach room temperature (15-30ºC) prior to testing. Instruct the donor not to place anything in the mouth including food, drink, gum, tobacco products for at least 10 minutes prior to collection.**

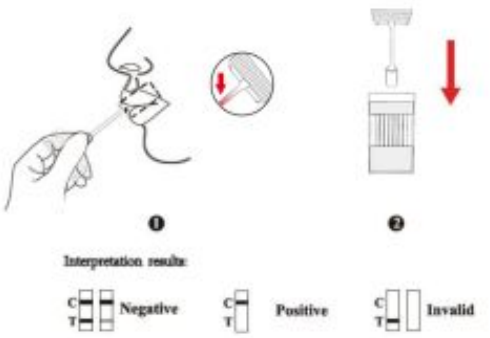
1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Using the provided collection swab, remove the collector from the sealed pouch, have donor sweep inside of mouth (cheek, gum, tongue) several times, then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. **Important:** Do not bite, suck, or chew on the sponge.

   **Note:** If after 7 minutes, color on the saturation indicator has not appeared in the indicator window, proceed with the test below. (See illustration 1)
3. Place the test device on a clean and flat surface. Remove the collection sponge from the mouth and insert the sponge first into the screening device **gently and slowly**, press until the collector cap locks in place and is secure. **Keep upright when inserting the sponge.** (See illustration 2)
4. **Keep Test device upright on flat surface and keep upright while test is running.** Wait for the colored signal to appear in test results area. Read the results at 10 minutes.

**Note: 1, Once the collection sponge locks in place, the device is airtight, tamper evident, and ready to be disposed of or sent to a laboratory for confirmation (on presumptive positive result).**

**2, If the strips do not wick, please peel off the label at the bottom of the device as marked to check if there is enough specimen (obviously specimen residue) or the oral fluid is too thick or viscous to run.**

**3, In the case of no flow when enough oral fluid , or the oral fluid is too thick to run, move the device while keeping upright and not tilting back and forth on a flat and clean surface several times until the oral fluid flows up the strip (peel off the specimen label to check and make sure the oral fluid is touching the strips). Do not tilt the device when the test is running before reading 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 indicates 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 Cube 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 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 oral fluid specimens were tested using the oral fluid Multi-Drug Test cube were compared to a 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 | BAR 50 | BAR 300 | BZO 10 | BZO 50 | BUP5 | BUP10 |
|---|---|---|---|---|---|---|---|
| Positive | 100% | 100% | 100% | 100% | 100% | 98.20% | 100% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 97.70% |
| Total | >99% | >99% | >99% | >99% | >99% | 98.99% | 98.99% |

| Specimen | COC | COD | MDMA | THC 12 | THC 25 | THC 50 |
|---|---|---|---|---|---|---|
| Positive | 100% | 100% | 100% | 100% | 92.86% | 96.40% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | >99% | >99% | >99% | >99% | 96% | 98% |

| Specimen | MTD 30 | MTD 75 | MET | MQL 150 | MQL 100 | OPI 15 | OPI 40 |
|---|---|---|---|---|---|---|---|
| Positive | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Negative | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| Total | >99% | >99% | >99% | >99% | >99% | >99% | >99% |

| Specimen | OXY 50 | OXY 20 | PPX | TCA |
|---|---|---|---|---|
| Positive | 100% | 100% | 100% | 100% |
| Negative | 100% | 100% | 100% | 97.70% |
| Total | >99% | >99% | >99% | 98.99% |

### 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 Cube. The results are summarized below.

| Drug Conc. | AMP | | BAR 50 | | BAR 300 | | BZO 10 | | BZO 50 | | BUP5 | | BUP10 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (Cut-off range) | - | + | - | + | - | + | - | - | + | + | - | + | - | + |
| 0% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 30 | 0 | 0 | 30 | 0 | 30 | 0 |
| -50% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 30 | 0 | 0 | 30 | 0 | 30 | 0 |
| +50% Cut-off | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 0 | 30 | 30 | 0 | 30 | 0 | 30 |

| Drug Conc. | COC | | COD | | MDMA | | THC 12 | | THC 25 | | THC 50 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (Cut-off range) | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% Cut-off | 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 |
| +50% Cut-off | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 1 | 29 | 0 | 30 |

| Drug Conc. | MTD 30 | | MTD 75 | | MET | | MQL 100 | | MQL 150 | | OPI 15 | | OPI 40 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (Cut-off range) | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| 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 | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 |

| Drug Conc. | OXY 20 | | OXY 50 | | PPX | | TCA | |
|---|---|---|---|---|---|---|---|---|
| (Cut-off range) | - | + | - | + | - | + | - | + |
| 0% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 |
| -50% Cut-off | 30 | 0 | 30 | 0 | 30 | 0 | 30 | 0 |
| +50% Cut-off | 0 | 30 | 0 | 30 | 0 | 30 | 0 | 30 |

## Analytical Specificity and Cross Reactivity

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

| Drug Compound | Concentration (ng/mL) |
|---|---|
| **AMPHETAMINE (AMP)** | |
| d-Amphetamine | 50 |
| d, l-Amphetamine | 125 |
| β-Phenylethylamine | 4,000 |
| Tryptamine | 1,500 |
| p-Hydroxyamphetamine | 800 |
| (+) 3,4-Methylenedioxyamphetamine (MDA) | 150 |
| l-Amphetamine | 4,000 |
| **BARBITURATE (BAR 50)** | |
| Secobarbital | 50 |
| Amobarbital | 100 |
| Alphenal | 100 |
| Aprobarbital | 30 |
| Butabarbital | 30 |
| Butalbital | 400 |
| Butethal | 30 |
| Cyclopentobarbital | 60 |
| Pentobarbital | 150 |
| Phenobarbital | 30 |
| **BARBITURATE (BAR 300)** | |
| Secobarbital | 300 |
| Amobarbital | 300 |
| Alphenal | 150 |
| Aprobarbital | 200 |
| Butabarbital | 75 |
| Butalbital | 2,500 |
| Butethal | 100 |
| Cyclopentobarbital | 600 |
| Pentobarbital | 300 |
| Phenobarbital | 100 |
| **BENZODIAZEPINES (BZO 10)** | |
| Oxazepam | 10 |
| Alprazolam | 6 |
| Bromazepam | 12 |
| Chlordiazepoxide | 12 |
| Clobazam | 6 |
| Clorazepate | 25 |
| Delorazepam | 25 |
| Desalkylflurazepam | 25 |

| Drug Compound | Concentration (ng/mL) |
|---|---|
| Diazepam | 3 |
| Estazolam | 3 |
| Flunitrazepam | 100 |
| α-Hydroxyalprazolam | 200 |
| (±)-Lorazepam | 200 |
| Midazolam | 25 |
| Nitrazepam | 12 |
| Norchlordiazepoxide | 200 |
| Nordiazepam | 25 |
| Temazepam | 6 |
| Triazolam | 25 |
| **BENZODIAZEPINES (BZO 50)** | |
| Oxazepam | 50 |
| Alprazolam | 300 |
| Bromazepam | 60 |
| Chlordiazepoxide | 60 |
| Clobazam | 36 |
| Clorazepate | 125 |
| Delorazepam | 125 |
| Desalkylflurazepam | 12 |
| Diazepam | 15 |
| Estazolam | 15 |
| Flunitrazepam | 500 |
| α-Hydroxyalprazolam | 1,000 |
| (±)-Lorazepam | 1,000 |
| Midazolam | 125 |
| Nitrazepam | 60 |
| Norchlordiazepoxide | 1,000 |
| Nordiazepam | 125 |
| Temazepam | 30 |
| **BUPRENORPHINE (BUP 5)** | |
| Buprenorphine | 5 |
| Buprenorphine-3-D-Glucuronide | 10 |
| Norbuprenorphine | 5 |
| Buprenorphine-3-D-Glucuronide | 10 |
| Buprenorphine Glucuronide | 20 |
| **BUPRENORPHINE (BUP 10)** | |
| Buprenorphine | 10 |
| Buprenorphine-3-D-Glucuronide | 10 |
| Norbuprenorphine | 20 |
| Buprenorphine-3-D-Glucuronide | 200 |
| Buprenorphine Glucuronide | 10 |
| **COCAINE (COC)** | |
| Benzoylecgonine | 20 |
| Cocaine | 20 |
| Cocaethylene | 25 |
| Ecgonine | 1,500 |
| Ecgonine methyl ester | 12,500 |
| N-Acetylprocainamide | 12,500 |
| Chlordiazepoxide | 12,500 |

| Drug Compound | Concentration (ng/mL) |
|---|---|
| **CODEINE (COD)** | |
| Codeine | 10 |
| Ranitidine | 6,250 |
| Heroin | 30 |
| Dihydrocodeine HCL | 15 |
| Ethyl Morphine | 10 |
| Hydrocodone | 62.5 |
| Hydromorphone | 31.25 |
| Levorphanol | 250 |
| Heroin Hydromorphone | 30 |
| 6-acetylmorphine | 25 |
| Nalorphine | 1,562.5 |
| Normorphine | 6,250 |
| Norcodeine | 2,000 |
| **ECSTASY (MDMA)** | |
| 3,4-Methylenedioxymethamphetamine | 50 |
| Butylone HCl | 6,250 |
| Ephedrine HCL | 12,500 |
| Ethylone | 12,500 |
| Phentermine | 12,500 |
| l-Methamphetamine | 1,562.5 |
| Methylone HCL | 50,000 |
| 3,4-Methylenedioxyamphetamine (MDA) | 781.25 |
| 3,4-Methylenedioxyethylampheta mine (MDEA) | 97.7 |
| (1R,2S)- (-)-Ephedrine | 3,125 |
| **MARIJUANA (THC 12)** | |
| 11-nor-$\Delta^9$-THC-9 COOH | 12 |
| Cannabinol | 31,500 |
| 11-nor-$\Delta^8$-THC-9 COOH | 2 |
| $\Delta^8$-THC | 6,000 |
| $\Delta^9$-THC | 20,000 |
| **MARIJUANA (THC 25)** | |
| $\Delta^9$-Tetrahydrocannabinol | 25 |
| 11-nor-$\Delta^9$ -THC-9 COOH | 15 |
| **MARIJUANA (THC 50)** | |
| $\Delta^9$-Tetrahydrocannabinol | 50 |
| $\Delta^8$-Tetrahydrocannabinol | 75 |
| 11-nor-$\Delta^9$-THC-9 COOH | 15 |
| 11-hydroxy-$\Delta^9$-THC | 300 |
| Cannabinol | 2,000 |
| Cannabidiol | >10,000 |
| **METHADONE (MTD 30)** | |
| Methadone | 30 |
| Doxylamine | 50,000 |
| Estrone-3-Sulfate | 50,000 |
| Phencyclidine | 50,000 |
| **METHADONE (MTD 75)** | |
| Methadone | 75 |
| Doxylamine | 100,000 |
| Estrone-3-sulfate | 100,000 |

| Drug Compound | Concentration (ng/mL) |
|---|---|
| Phencyclidine | 100,000 |
| **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 |
| **METHAQUALONE (MQL 100)** | |
| Methaqualone | 100 |
| **METHAQUALONE (MQL 150)** | |
| Methaqualone | 150 |
| **OPIATE (OPI)** | |
| Morphine | 15 |
| Codeine | 15 |
| Ethyl morphine | 15 |
| Hydromorphone | 50 |
| Hydrocodone | 50 |
| Morphine 3-β-d-glucuronide | 30 |
| Nalorphine | 300 |
| Oxymorphone | 25,000 |
| Thebaine | 5,000 |
| Diacetylmorphine (Heroin) | 15 |
| 6-Monoacetylmorphine (6-MAM) | 15 |
| **OPIATE (OPI)** | |
| Morphine | 40 |
| Codeine | 10 |
| Ethyl morphine | 24 |
| Hydromorphone | 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) | 25 |
| Bilirubin | 3,500 |
| **OXYCODONE (OXY 20)** | |
| Oxycodone | 20 |
| Dihydrocodeine HCL | 3,125 |

| Drug Compound | Concentration (ng/mL) |
|---|---|
| Gatifloxacin | 25,000 |
| Hydrocodone | 1,562.5 |
| Hydromorphone | 781.25 |
| Heroin | 12,500 |
| Oxymorphone-D3 | 390.6 |
| Oxymorphone | 48.8 |
| Naltrexone hydrochloride | 3,125 |
| **OXYCODONE (OXY 50)** | |
| Oxycodone | 50 |
| Dihydrocodeine HCL | 6,250 |
| Gatifloxacin | 60,000 |
| Hydrocodone | 6,250 |
| Hydromorphone | 1,562 |
| Heroin | 25,000 |
| Oxymorphone-D3 | 781 |
| Oxymorphone | 100 |
| Naltrexone hydrochloride | 6,250 |
| **PROPOXYPHENE (PPX)** | |
| Propoxyphene (PPX) | 50 |
| D-Norpropoxyphene | 200 |
| **TRICYCLIC ANTIDEPRESSANTS (TCA)** | |
| Nortriptyline | 100 |
| Amitriptyline | 250 |
| Clomipramine | 5,000 |
| Desipramine | 20 |
| Doxepin | 30 |
| Imipramine | 2,000 |
| Maprotiline | 10,000 |
| Nordoxepin | 1,500 |
| Promazine | 6,000 |
| Promethazine | 500 |
| Trimipramine | 5,000 |
| Cyclobenzaprine Hydrochloride | 500 |
| Norclomipramine | 5,000 |

## Interference

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

## Non-Cross-Reacting Compounds

| | | | |
|---|---|---|---|
| Acetaminophen | Diclofenac | Loperamide | d-Pseudoephedrine |
| Acetophenetidin | Dicyclomine | Meprobamate | Quinacrine |
| Acetylsalicylic acid | Diflunisal | Methylphenidate | Quinine |
| Aminopyrine | Digoxin | Nalidixic acid | Quinidine |
| 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 | Phenylpropanolamined, 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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