



## Oral Fluid Drug Test Cube Package Insert For Forensic Use Only

Package insert for testing oral fluid for any combination of the following drugs:  
Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Cotinine, Ecstasy, EDDP, Fentanyl, Heroin (6-MAM), Ketamine, Lysergic acid diethylamide, Marijuana, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone (MDPV), Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Synthetic Cannabinoid (K2), Tramadol, Tricyclic Antidepressants and Alcohol.

This device has various combinations. Please refer to product labeling for exact drug panels and cutoffs.

### INTENDED USE & SUMMARY

The Oral Fluid Drug Test Cube is intended for screening for the presence of drugs and alcohol 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 human 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)                     | Benzoyllecgonine                                 | 20              |
| Cotinine (COT)                    | Cotinine                                         | 30/50           |
| Ecstasy (MDMA)                    | 3,4-Methylenedioxymethamphetamine                | 50              |
| Fentanyl (FEN)                    | Norfentanyl                                      | 10              |
| Heroin (6-MAM)                    | 6-Monoacetylmorphine                             | 10/15           |
| Ketamine (KET)                    | Ketamine                                         | 50/100          |
| Lysergic acid diethylamide (LSD)  | d-Lysergic acid diethylamide                     | 25              |
| Marijuana Metabolite (THC)        | 11-nor- $\Delta^9$ -THC-9 COOH                   | 3/12            |
| Marijuana (THC)                   | $\Delta^9$ -THC                                  | 25/40           |
| Methadone Metabolite (EDDP)       | 2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine | 20              |
| Methadone (MTD)                   | Methadone                                        | 30/75           |
| Methamphetamine (MET)             | D-Methamphetamine                                | 50              |
| Methaqualone (MQL)                | Methaqualone                                     | 100/150         |
| Methylenedioxypyrovalerone (MDPV) | Methylenedioxypyrovalerone                       | 50/100          |
| Morphine (MOP)                    | Morphine                                         | 15              |
| Opiates (OPI)                     | Morphine                                         | 40              |
| Oxycodone (OXY)                   | Oxycodone                                        | 20/50           |
| Phencyclidine (PCP)               | Phencyclidine                                    | 10              |
| Propoxyphene (PPX)                | Propoxyphene                                     | 50              |
| Synthetic Cannabinoid (K2)        | JWH-073/JWH-018                                  | 5               |
| Tramadol (TRA)                    | Tramadol                                         | 50              |
| Tricyclic Antidepressants (TCA)   | Nortriptyline                                    | 100             |
| Alcohol (ALC)                     | Alcohol                                          | > 0.02 % B.A.C  |

This test will detect other related compounds and metabolites, 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.<sup>1</sup>

**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.

**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. 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.

**COC:** Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (*Erythroxylum coca*).<sup>1</sup>

**COT:** Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

**MDMA:** MDMA is an abbreviation for the chemical methylenedioxymethamphetamine. It has street many name including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, 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. MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the effects of MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours. It is detectable in the saliva for up to 3 days after use.

**FEN:** Fentanyl, belongs to powerful narcotics analgesics, and is a special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain.<sup>1</sup> After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc.<sup>2,3</sup>

**KET:** Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug.

**LSD:** D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram.

**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).<sup>2</sup>

**EDDP:** EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is formed by N-demethylation and cyclization of methadone in the liver. The detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

**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 saliva/plasma ratio calculated over salivary pH ranges of 6.4-7.6 for therapeutic or recreational doses of methadone.

**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.<sup>1</sup>

**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 on countries in combination with diphenhydramine (Mandrax).

**MDPV:** "Bath salts", a form of designer drugs, also promoted as 'plant food' or 'research chemicals' and is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a 'legal' high. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. The white crystals resemble legal bathing salts, thus the name of 'bath salts'.

**6-MAM:** 6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excrete. Since 6-MAM is a unique metabolite to heroin, its presence in the saliva confirms that heroin was the opioid used. This is significant because on a saliva immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulfate, and heroin.

**OPI:** 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.<sup>3</sup>

\*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.

**PCP:** Phencyclidine is a hallucinogen and, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity.<sup>5</sup>

**PPX:** Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. 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).

**K2:** Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice. As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47, JWH-200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", "K3" and others. These products may be smoked for their psychoactive effects.

**TRA:** Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine but has a low binding affinity to thermu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.<sup>2</sup>

**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.

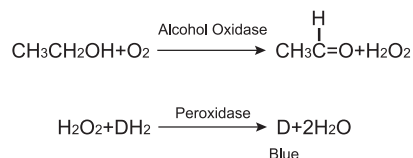
**ALC:** Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (20 mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

**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/Mass Spectrometry/ 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

(1) 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. A procedural control, will appear as colored line at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:



#### REAGENTS

(1) 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.

(2) Alcohol Test: The alcohol pad contains Tetramethylbenzidine, Alcohol oxidase, Peroxidase, Buffer and Stabilizing Proteins.

#### PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not reuse the test.
- 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.
- Safety data sheets are available upon request

#### 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 by the collection swab provided within 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. If specimen cannot be tested immediately, it is recommended that specimen be stored at 2-8°C or -20°C for up to 72 hours. Specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimen using ice packs (2-8°C). Perform testing immediately after collection.

#### MATERIALS

##### Materials Provided

- Test cubes
- Collection swabs
- Procedure card
- Security seal labels
- Package insert
- Color chart cards for alcohol (when applicable)

##### Materials Required But Not Provided

- Timer
- Gloves

#### DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

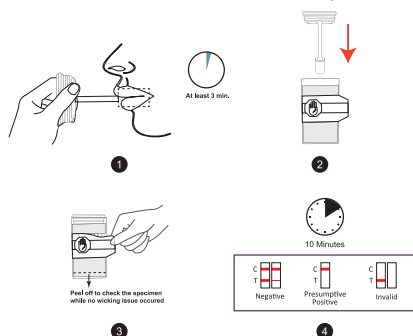
Remove the collection swab from packaging. Start Timer. Relax the mouth and insert the collection swab into the mouth. The collection swab must be horizontal throughout the collection process. Using a circular motion, gently swab both cheeks 5-10 times, gums 5-10 times, and surface of tongue 5-10 times, actively swab the inside the mouth, top of tongue, and between cheek and gum. Collect oral fluid for at least 3 minutes until sponge is soft and fully saturated. No hard spots should be felt on the sponge when saturated, continue to collect the sample if a hard spot is present.

**Important:** Do not bite, suck, or chew on the sponge. It is critical that the collector is held horizontally during collection, otherwise there will be insufficient saliva collected. During collection of the oral fluid, relax the mouth while swabbing the tongue and check as this will aid in the collection of the oral fluid. (See illustration 1)

- Remove test device from sealed pouch and place upright on a clean, flat surface. **Gently and slowly** insert the collection swab into the test device, sponge first, until it reaches the bottom of the test device and collector cap locks in place and is secure. (See illustration 2)

**Important:** Keep test device upright while inserting collection swab. Once the collection swab is locked in place, the test device is airtight, tamper evident and ready to be shipped to a lab for confirmation if required. Alternatively, the test device can be disposed of.

- Keep test device upright on a flat surface until the test is complete. Start timer. **Important: If any test strips do not develop (invalid), peel away bottom of device label to inspect specimen volume. Refer to Notes and Troubleshooting.**
- Interpret results at 10 minutes. If positive results are observed, apply the security seal label from cap down to sides of the device, then send the device to a laboratory for confirmation.



#### NOTES AND TROUBLESHOOTING

Invalid results may occur, if the strips do not wick, peel off the label at the bottom of the device as marked to check if either there is enough specimen, or the oral fluid is too thick or viscous to run.

a.) If strips do not appear to flow when there is enough oral fluid, or the oral fluid is too thick to run move the device back and forth several times across a flat, clean surface. Ensure the device remains upright. Do not tilt the device when the test is running before reading results.

b.) Oral fluid tends to form air bubbles which sit at the bottom of the strip and prevent the strip from running. Gently tap the device on the table or counter surface popping the air bubble allowing capillary action to begin, thus initiating the test.

#### 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.

#### Alcohol Test Results

**Alcohol Negative Result:** The alcohol pad shows no color change (remains white or cream colored); it should be interpreted as a negative result (no alcohol present). A result where the outer edges of the alcohol pad produces a slight color, but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

**Alcohol Presumptive Positive Result:** The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02% B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

#### QUALITY CONTROL

The colored line appearing in the control region (C) is considered the internal procedural control. It confirms sufficient specimen volume and adequate membrane wicking. 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

- 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.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- A negative result may not necessarily indicate a drug-free specimen. Drug(s) may be present in the specimen below the cut-off level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- A positive result may be obtained from certain foods or food supplements.

#### PERFORMANCE CHARACTERISTICS

##### Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of  $\pm 50\%$  cut-off and tested with the Oral Fluid Drug Test Cube. The results are summarized below.

| Drug Conc. (Cut-off range) | AMP | BAR 50 | BAR 300 | BZO 10 | BZO 50 | BUP 5 | BUP 10 |
|----------------------------|-----|--------|---------|--------|--------|-------|--------|
|                            | - + | - +    | - +     | - +    | - +    | - +   | - +    |

|                               |              |    |         |    |        |    |         |    |         |    |          |    |          |    |     |    |   |
|-------------------------------|--------------|----|---------|----|--------|----|---------|----|---------|----|----------|----|----------|----|-----|----|---|
| 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.<br>(Cut-off range) | COC          |    | COT 30  |    | COT 50 |    | MDMA    |    | FEN     |    | 6-MAM 10 |    | 6-MAM 15 |    |     |    |   |
|                               | -            | +  | -       | +  | -      | -  | -       | +  | -       | +  | -        | +  | -        | +  |     |    |   |
|                               | 0% Cut-off   | 30 | 0       | 30 | 0      | 30 | 30      | 0  | 30      | 0  | 30       | 0  | 30       | 0  |     |    |   |
|                               | -50% Cut-off | 30 | 0       | 30 | 0      | 30 | 30      | 0  | 30      | 0  | 30       | 0  | 30       | 0  |     |    |   |
|                               | +50% Cut-off | 0  | 30      | 0  | 30     | 0  | 0       | 0  | 30      | 0  | 30       | 0  | 30       | 0  |     |    |   |
| Drug Conc.<br>(Cut-off range) | KET 50       |    | KET 100 |    | LSD    |    | THC 3   |    | THC 25  |    | THC 40   |    | EDDP     |    |     |    |   |
|                               | -            | +  | -       | +  | -      | +  | -       | +  | -       | +  | -        | +  | -        | +  |     |    |   |
|                               | 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      | 1  | 29       | 0  | 30       | 0  | 30  |    |   |
| Drug Conc.<br>(Cut-off range) | MTD 30       |    | MTD 75  |    | MET    |    | MQL 100 |    | MQL 150 |    | MDPV 50  |    | MDPV 100 |    | MOP |    |   |
|                               | -            | +  | -       | +  | -      | -  | -       | +  | -       | +  | -        | +  | -        | +  | -   | +  |   |
|                               | 0% Cut-off   | 30 | 0       | 30 | 0      | 30 | 30      | 0  | 30      | 0  | 30       | 0  | 30       | 0  | 30  | 0  |   |
|                               | -50% Cut-off | 30 | 0       | 30 | 0      | 30 | 30      | 0  | 30      | 0  | 30       | 0  | 30       | 0  | 30  | 0  |   |
|                               | +50% Cut-off | 0  | 30      | 0  | 30     | 0  | 0       | 0  | 30      | 0  | 30       | 0  | 30       | 0  | 30  | 0  |   |
| Drug Conc.<br>(Cut-off range) | OPI          |    | OXY 20  |    | OXY 50 |    | PCP     |    | PPX     |    | K2       |    | TRA      |    | TCA |    |   |
|                               | -            | +  | -       | +  | -      | +  | -       | +  | -       | +  | -        | +  | -        | +  | -   | +  |   |
|                               | 0% Cut-off   | 30 | 0       | 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   | 30 | 0 |
|                               | +50% Cut-off | 0  | 30      | 0  | 30     | 0  | 0       | 30 | 0       | 30 | 0        | 30 | 0        | 30 | 0   | 30 | 0 |
| Drug Conc.<br>(Cut-off range) | THC 12       |    |         |    |        |    |         |    |         |    |          |    |          |    |     |    |   |
|                               | -            | +  |         |    |        |    |         |    |         |    |          |    |          |    |     |    |   |
|                               | 0% Cut-off   | 30 | 0       |    |        |    |         |    |         |    |          |    |          |    |     |    |   |
|                               | -50% Cut-off | 30 | 0       |    |        |    |         |    |         |    |          |    |          |    |     |    |   |
|                               | +50% Cut-off | 0  | 30      |    |        |    |         |    |         |    |          |    |          |    |     |    |   |

**Analytical Specificity**

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) |
|---------------------------------------|-----------------------|
| <b>AMPHETAMINE (AMP)</b>              |                       |
| d-Amphetamine                         | 50                    |
| Phentermine                           | 120,000               |
| R(-)-Amphetamine                      | 10,000                |
| (±)-Amphetamine                       | 50                    |
| Serotonin                             | 500,000               |
| Octopamine                            | 60,000                |
| (±)-Phenylpropanolamine hydrochloride | 100,000               |
| Tryptamine                            | 1,500                 |
| <b>BARBITURATE (BAR 50)</b>           |                       |
| Secobarbital                          | 50                    |
| Amobarbital                           | 100                   |
| Alphenal                              | 100                   |
| Aprobarbital                          | 30                    |
| Butabarbital                          | 30                    |
| Butalbital                            | 400                   |
| Butethal                              | 30                    |
| Cyclopentobarbital                    | 60                    |
| Pentobarbital                         | 150                   |
| Phenobarbital                         | 30                    |
| <b>BARBITURATE (BAR 300)</b>          |                       |

| Drug Compound                   | Concentration (ng/mL) |
|---------------------------------|-----------------------|
| Secobarbital                    | 300                   |
| Amobarbital                     | 300                   |
| Alphenal                        | 150                   |
| Aprobarbital                    | 200                   |
| Butabarbital                    | 75                    |
| Butalbital                      | 2,500                 |
| Butethal                        | 100                   |
| Cyclopentobarbital              | 600                   |
| Pentobarbital                   | 300                   |
| Phenobarbital                   | 100                   |
| <b>BENZODIAZEPINES (BZO 10)</b> |                       |
| Oxazepam                        | 10                    |
| Alprazolam                      | 6                     |
| Bromazepam                      | 12                    |
| Chlordiazepoxide                | 12                    |
| Clobazam                        | 6                     |
| Clorazepate                     | 25                    |
| Delorazepam                     | 25                    |
| Desalkylflurazepam              | 25                    |
| Diazepam                        | 3                     |
| Estazolam                       | 3                     |
| Flunitrazepam                   | 100                   |
| α-Hydroxyalprazolam             | 200                   |
| (±)-Lorazepam                   | 200                   |
| Midazolam                       | 25                    |
| Nitrazepam                      | 12                    |
| Norchlordiazepoxide             | 200                   |
| Nordiazepam                     | 25                    |
| Temazepam                       | 6                     |
| Triazolam                       | 25                    |
| <b>BENZODIAZEPINES (BZO 50)</b> |                       |
| 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                    |
| <b>BUPRENORPHINE (BUP 5)</b>    |                       |

| Drug Compound                              | Concentration (ng/mL) |
|--------------------------------------------|-----------------------|
| Buprenorphine                              | 5                     |
| Buprenorphine-3-D-Glucuronide              | 10                    |
| Norbuprenorphine                           | 5                     |
| Buprenorphine Glucuronide                  | 20                    |
| <b>BUPRENORPHINE (BUP 10)</b>              |                       |
| Buprenorphine                              | 10                    |
| Buprenorphine-3-D-Glucuronide              | 10                    |
| Norbuprenorphine                           | 20                    |
| Buprenorphine Glucuronide                  | 10                    |
| <b>COCAINE (COC)</b>                       |                       |
| Benzoylcegonine                            | 20                    |
| Cocaine                                    | 20                    |
| Cocaethylene                               | 25                    |
| Ecgonine                                   | 1,500                 |
| Ecgonine methyl ester                      | 12,500                |
| N-Acetylprocainamide                       | 12,500                |
| Norcocaine                                 | 500                   |
| <b>COTININE (COT 30)</b>                   |                       |
| (-) Cotinine                               | 30                    |
| S(-)-Nicotine                              | 3,000                 |
| Flephedrone(4-fluoromethcathinone)         | 50,000                |
| N-Benzylisopropylamine                     | 5,000                 |
| <b>COTININE (COT 50)</b>                   |                       |
| (-) Cotinine                               | 50                    |
| S(-)-Nicotine                              | 5,000                 |
| Flephedrone(4-fluoromethcathinone)         | 80,000                |
| N-Benzylisopropylamine                     | 8,000                 |
| <b>ECSTASY (MDMA)</b>                      |                       |
| 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                 |
| <b>FENTANYL (FEN)</b>                      |                       |
| Norfentanyl                                | 10                    |
| Fentanyl                                   | 20                    |
| Buspirone                                  | 12,500                |
| <b>HEROIN (6-MAM 10)</b>                   |                       |
| 6-Monoacetylmorphine (6-MAM)               | 10                    |
| Codeine                                    | >600,000              |
| Morphine                                   | >550,000              |
| Heroin                                     | 250                   |
| Diethylstilbestrol                         | 70,000                |
| Trimethoprim                               | 50,000                |
| <b>HEROIN (6-MAM 15)</b>                   |                       |

| Drug Compound                                           | Concentration (ng/mL) |
|---------------------------------------------------------|-----------------------|
| 6-Monoacetylmorphine (6-MAM)                            | 15                    |
| Codeine                                                 | >600,000              |
| Morphine                                                | >600,000              |
| Heroin                                                  | 250                   |
| Diethylstilbestrol                                      | 75,000                |
| Trimethoprim                                            | 52,000                |
| <b>KETAMINE (KET 50)</b>                                |                       |
| Ketamine                                                | 50                    |
| Norketamine                                             | 500                   |
| Dextroproporphane                                       | 25                    |
| Dextrophantratartrate                                   | 25                    |
| D-Norpropoxyphene                                       | 1,560                 |
| <b>KETAMINE (KET 100)</b>                               |                       |
| Ketamine                                                | 100                   |
| Norketamine                                             | 1,000                 |
| Dextroproporphane                                       | 70                    |
| Dextrophantratartrate                                   | 70                    |
| D-Norpropoxyphene                                       | 3,000                 |
| <b>LYSERGIC ACID DIETHYLAMIDE (LSD)</b>                 |                       |
| D-lysergic acid diethylamide                            | 25                    |
| Fentanyl                                                | 40                    |
| Norfentanyl                                             | 150                   |
| Risperidone                                             | 4,000                 |
| Prilocaine                                              | 8,000                 |
| <b>MARIJUANA (THC3)</b>                                 |                       |
| 11-nor- $\Delta^9$ -THC-9 COOH                          | 3                     |
| Cannabinol                                              | 7,500                 |
| 11-nor- $\Delta^8$ -THC-9 COOH                          | 2                     |
| $\Delta^8$ -THC                                         | 5,000                 |
| $\Delta^9$ -THC                                         | 4,500                 |
| <b>MARIJUANA (THC 12)</b>                               |                       |
| 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                |
| <b>MARIJUANA (THC 25)</b>                               |                       |
| $\Delta^9$ -Tetrahydrocannabinol                        | 25                    |
| $\Delta^8$ -Tetrahydrocannabinol                        | 50                    |
| 11-nor- $\Delta^9$ -THC-9 COOH                          | 3                     |
| 11-hydroxy- $\Delta^9$ -THC                             | 28                    |
| Cannabinol                                              | 125                   |
| Cannabidiol (CBD)                                       | 1,400                 |
| 11-Nor- $\Delta^9$ -THC-carboxy-glucuronide             | 40                    |
| (+)-11-nor-9-carboxy- $\Delta^9$ -THC                   | 30                    |
| 11-nor- $\Delta^8$ -THC-9-COOH                          | 12                    |
| 8-beta-11-dihydroxy- $\Delta^9$ -THC                    | 125                   |
| 8-beta-hydroxy- $\Delta^9$ -THC                         | 125                   |
| Exo-THC                                                 | 50                    |
| I-11-Nor- $\Delta^9$ -THC-9-Carboxylic Acyl-Glucuronide | 10                    |

| Drug Compound                                           | Concentration (ng/mL) |
|---------------------------------------------------------|-----------------------|
| $\Delta^8$ -THC Carboxylic Acid                         | 12                    |
| $\Delta^9$ -THC Carboxylic Acid                         | 2                     |
| <b>MARIJUANA (THC 40)</b>                               |                       |
| $\Delta^9$ -Tetrahydrocannabinol                        | 40                    |
| $\Delta^8$ -Tetrahydrocannabinol                        | 80                    |
| 11-nor- $\Delta^9$ -THC-9 COOH                          | 4                     |
| 11-hydroxy- $\Delta^9$ -THC                             | 45                    |
| Cannabinol                                              | 200                   |
| Cannabidiol (CBD)                                       | 2,200                 |
| 11-Nor- $\Delta^9$ -THC-carboxy-glucuronide             | 60                    |
| (+)-11-nor-9-carboxy- $\Delta^9$ -THC                   | 50                    |
| 11-nor- $\Delta^8$ -THC-9-COOH                          | 20                    |
| 8-beta-11-dihydroxy- $\Delta^8$ -THC                    | 200                   |
| 8-beta-hydroxy- $\Delta^9$ -THC                         | 200                   |
| Exo-THC                                                 | 75                    |
| I-11-Nor- $\Delta^9$ -THC-9-Carboxylic Acyl-Glucuronide | 15                    |
| $\Delta^8$ -THC Carboxylic Acid                         | 20                    |
| $\Delta^9$ -THC Carboxylic Acid                         | 4                     |
| <b>EDDP (EDDP)</b>                                      |                       |
| EDDP                                                    | 20                    |
| Meperidine                                              | 20,000                |
| Methadone                                               | 20,000                |
| Norfentanyl                                             | 20,000                |
| Phencyclidine                                           | 20,000                |
| Promazine                                               | 10,000                |
| Promethazine                                            | 5,000                 |
| Prothipendyl                                            | 10,000                |
| Prozine                                                 | 2,500                 |
| <b>METHADONE (MTD 30)</b>                               |                       |
| Methadone                                               | 30                    |
| Promethazine                                            | 30,000                |
| PCP(Phencyclidine)                                      | 5,000                 |
| Levorphanol                                             | 10,000                |
| Disopyramide                                            | 1,000                 |
| <b>METHADONE (MTD 75)</b>                               |                       |
| Methadone                                               | 75                    |
| Promethazine                                            | 39,000                |
| PCP(Phencyclidine)                                      | 6,500                 |
| Levorphanol                                             | 13,000                |
| Disopyramide                                            | 1,300                 |
| <b>METHAMPHETAMINE (MET)</b>                            |                       |
| d-Methamphetamine                                       | 50                    |
| Fenfluramine                                            | 60,000                |
| p-Hydroxymethamphetamine                                | 400                   |
| Methoxyphenamine                                        | 25,000                |
| 3,4-Methylenedioxymethamphetamine (MDMA)                | 50                    |
| I-Phenylephrine                                         | 4,000                 |
| Procaine                                                | 2,000                 |
| (1R,2S)- (-) Ephedrine                                  | 400                   |
| 1-Ephedrine                                             | 400                   |

| Drug Compound                                     | Concentration (ng/mL) |
|---------------------------------------------------|-----------------------|
| Mephentermine                                     | 800                   |
| (-) Deoxyephedrine, L-Methamphetamine             | 3,000                 |
| Ephedrine                                         | 800                   |
| 4-Methylethcathinone hydrochloride                | 25,000                |
| Ethylone hydrochloride                            | 25,000                |
| (+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA) | 100                   |
| (+/-)-Methylenedioxyamphetamine(MDA)              | 25,000                |
| D,L-Methamphetamine                               | 4,000                 |
| (±)-Amphetamine                                   | 10,000                |
| Acetylsalicylic                                   | 4,000                 |
| Chlorothiazide                                    | 25,000                |
| R(-)-Methamphetamine                              | 400                   |
| <b>METHAQUALONE (MQL 100)</b>                     |                       |
| Methaqualone                                      | 100                   |
| <b>METHAQUALONE (MQL 150)</b>                     |                       |
| Methaqualone                                      | 150                   |
| <b>METHYLENEDIOXYPYROVALERONE (MDPV 50)</b>       |                       |
| Methylenedioxypropylvalerone                      | 50                    |
| Butylone                                          | 4,000                 |
| Ethylone                                          | 50                    |
| Methylone                                         | 11,000                |
| Brompheniramine                                   | 800                   |
| Methedrone                                        | 5,000                 |
| Naphyrone                                         | >100,000              |
| Flephedrone                                       | >100,000              |
| <b>METHYLENEDIOXYPYROVALERONE (MDPV 100)</b>      |                       |
| Methylenedioxypropylvalerone                      | 100                   |
| Butylone                                          | 5,000                 |
| Ethylone                                          | 50                    |
| Methylone                                         | 10,000                |
| Brompheniramine                                   | 1,000                 |
| Methedrone                                        | 5,000                 |
| Naphyrone                                         | >100,000              |
| Flephedrone                                       | >100,000              |
| <b>MORPHINE (MOP)</b>                             |                       |
| Morphine                                          | 15                    |
| Codeine                                           | 15                    |
| Ethyl morphine                                    | 15                    |
| Hydromorphone                                     | 50                    |
| Hydrocodone                                       | 50                    |
| Morphine 3- $\beta$ -d-glucuronide                | 30                    |
| Nalorphine                                        | 300                   |
| Oxymorphone                                       | 25,000                |
| Thebaine                                          | 5,000                 |
| Diacetylmorphine (Heroin)                         | 15                    |
| 6-Monoacetylmorphine (6-MAM)                      | 15                    |
| Oxycodone                                         | 12,500                |
| <b>OPIATE (OPI)</b>                               |                       |
| Morphine                                          | 40                    |
| Codeine                                           | 10                    |

| Drug Compound                                   | Concentration (ng/mL) |
|-------------------------------------------------|-----------------------|
| 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                 |
| 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                 |
| PHENCYCLIDINE (PCP)                             |                       |
| Phencyclidine                                   | 10                    |
| Tetrahydrozoline                                | 50,000                |
| PROPOXYPHENE (PPX)                              |                       |
| Propoxyphene (PPX)                              | 50                    |
| D-Norpropoxyphene                               | 200                   |
| SYNTHETIC CANNABINOID (K2)                      |                       |
| JWH-018 5-Pentanoic acid metabolite             | 5                     |
| JWH-073 4-butanoic acid metabolite              | 5                     |
| JWH-250 4-Hydroxypentyl metabolite              | 25,000                |
| JWH-210 5-Hydroxypentyl metabolite              | 50,000                |
| JWH-073 4-Hydroxybutyl metabolite               | 250                   |
| JWH-019 5-hydroxyhexyl metabolite               | 5,000                 |
| JWH-018 N-(4-hydroxypentyl) metabolite solution | 500                   |
| JWH-019 6-Hydroxyhexyl                          | 700                   |
| JWH-019 5-Hydroxyhexyl                          | 400                   |

| Drug Compound                      | Concentration (ng/mL) |
|------------------------------------|-----------------------|
| MAM2201                            | 40,000                |
| JWH-122 5-Hydroxypentyl metabolite | 700                   |
| APINACA 5-hydroxypentyl metabolite | 50,000                |
| TRAMADOL (TRA)                     |                       |
| Tramadol                           | 50                    |
| N-desmethyltramadol                | 260                   |
| O-desmethyltramadol                | 12,000                |
| 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                 |

**Alcohol Test**  
The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

**Interference Compounds**

A study was conducted to determine the interference compounds of the test 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-interfering Compounds Tables**

|                      |                        |                      |                     |
|----------------------|------------------------|----------------------|---------------------|
| Acetaminophen        | Diclofenac             | Loperamide           | d-Pseudoephedrine   |
| Acetophenetidin      | Dicyclomine            | Meprobamate          | Quinacrine          |
| Acetylsalicylic acid | Diflunisal             | Methylphenidate      | Quinine             |
| Aminopyrine          | Digoxin                | Nalidixic acid       | Quindine            |
| 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           | lproniazid        | Phenylpropanolamine | d,l-Tryptophan  |
| Cortisone           | (-)-Isoproterenol | Prednisolone        | Tyramine        |
| Creatinine          | Isosuprine        | Phenolbarbital      | Uric acid       |
| Deoxycorticosterone | Ketoprofen        | Prednisone          | Verapamil       |
| Dextromethorphan    | Labetalol         | d,l-Propranolol     | Zomepirac       |

**Alcohol Test**  
The following substances may interfere with the Oral Fluid Drug Test Cube when using samples other than oral fluid:  
(1) Agents which enhance color development: Peroxides and strong oxidizers  
(2) Agents which inhibit color development:

Reducing Agents: such as Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptanals and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methyl dopa, L-dopa, L-methyl dopa, and Methampryone, etc. The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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Revision Date: 2024-12-24  
B23847-01