



## Oral Fluid Drug Test Cube Package Insert

Package insert for testing of the following drugs:

Amphetamine 50, Barbiturates 50, Benzodiazepine 10, Cocaine 20, Marijuana 12, Methadone 30, Methamphetamine 50, Morphine 15, Opiate 40, Propoxyphene 50.

**For employment and insurance use.**

**For forensic use.**

### INTENDED USE & SUMMARY

The InstaCube Oral Fluid Drug Test Cube is intended for screening for the presence of drugs and their metabolites in oral fluid. For professional *in vitro* diagnostic use only.

The InstaCube Oral Fluid Drug Cube Test is a lateral flow chromatographic immunoassay for the qualitative 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              |
| Benzodiazepine (BZO)  | Oxazepam                       | 10              |
| Cocaine (COC)         | Benzoyllecgonine               | 20              |
| Marijuana (THC)       | 11-nor- $\Delta^9$ -THC-9 COOH | 12              |
| Methadone (MTD)       | Methadone                      | 30              |
| Methamphetamine (MET) | D-Methamphetamine              | 50              |
| Morphine (MOP)        | Morphine                       | 15              |
| Opiates (OPI)         | Morphine                       | 40              |
| Propoxyphene (PPX)    | Propoxyphene                   | 50              |

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.<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. 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.

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

**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.<sup>2</sup>

**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, 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.<sup>1</sup>

**OPI (MOP):** The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates 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.

**PPX:** Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. 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.

**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.**

### PRINCIPLE

The InstaCube 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 InstaCube 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. For forensic 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.
- Safety data sheets available for professional user 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 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. 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).

### MATERIALS

#### Materials Provided

- Test devices
- Saliva collectors
- Security seal labels
- Package insert

#### Materials Required But Not Provided

- Timer
- Gloves

### DIRECTIONS FOR USE

**Allow the test device, specimen, 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.**

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. Remove the collector from the sealed pouch, insert the sponge into the mouth. Close mouth and move the sponge around for oral fluid collection. Soak sponge (do not bite, suck or chew on the sponge), in oral fluid and swab the inside of the mouth and tongue. Collect oral fluid for **7 minutes** or

until sponge is soft and fully saturated. **No hard spots should be felt on the sponge when saturated.** (See illustration 1)

- Place the test device on a clean and flat surface. Remove the collection sponge from mouth and insert **gently** into the screening device, press until the collector cap is sealed with the device **tightly**. **Keep upright when inserting and pressing the sponge.** (See illustration 2)
- 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. Do not interpret results after 15 minutes.

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

2, **If no wicking issue occurred, please peel off the label at the bottom of the device as marked to check if there is enough specimen (obvious specimen residue) or the saliva is too thick or viscous to run.**

3, **In the case of no flowing even with enough saliva specimen, or the saliva is too thick to run, please move the device (keep upright, don't tilt) back and forth on a flat and clean surface for several times until saliva flows up. Do not tilt when the test is running before**



Interpretation results:



**INSTACUBE**

### 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 indicate 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

- The InstaCube 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 gas chromatography/tandem mass spectrometry (GC/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 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 InstaCube Oral Fluid Drug Test Cube. The results are summarized below.

| Drug Conc.<br>(Cut-off range) | AMP 50 |    | COC 20 |    | BAR 50 |    | THC 12 |    | MTD 30 |    | BZO 10 |    |
|-------------------------------|--------|----|--------|----|--------|----|--------|----|--------|----|--------|----|
|                               | -      | +  | -      | +  | -      | +  | -      | +  | -      | +  | -      | +  |
| 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  |
| Cut-off                       | 15     | 15 | 14     | 16 | 14     | 16 | 16     | 14 | 14     | 16 | 15     | 15 |
| +50% Cut-off                  | 0      | 30 | 0      | 30 | 0      | 30 | 0      | 30 | 0      | 30 | 0      | 30 |
| 3X Cut-off                    | 0      | 30 | 0      | 30 | 0      | 30 | 0      | 30 | 0      | 30 | 0      | 30 |

| Drug Conc.<br>(Cut-off range) | MOP |    | OPI |    | PPX |    | MET |    |
|-------------------------------|-----|----|-----|----|-----|----|-----|----|
|                               | -   | +  | -   | +  | -   | +  | -   | +  |
| 0% Cut-off                    | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  |
| -50% Cut-off                  | 30  | 0  | 30  | 0  | 30  | 0  | 30  | 0  |
| Cut-off                       | 14  | 16 | 15  | 15 | 15  | 15 | 14  | 16 |
| +50% Cut-off                  | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 |
| 3X Cut-off                    | 0   | 30 | 0   | 30 | 0   | 30 | 0   | 30 |

#### Analytical Specificity

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

| AMPHETAMINE (AMP 50)                    |        |
|---|--------|
| d-Amphetamine                           | 50     |
| d,l-Amphetamine                         | 125    |
| $\beta$ -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     |
| Butobarbital                            | 30     |
| Butalbital                              | 400    |
| Butethal                                | 30     |
| Cyclopentobarbital                      | 60     |
| Pentobarbital                           | 150    |
| Phenobarbital                           | 30     |
| COCAINE (COC 20)                        |        |
| Benzoyllecgonine                        | 20     |
| Cocaine                                 | 20     |
| Cocaethylene                            | 25     |
| Ecgonine                                | 1,500  |
| Ecgoninemethylester                     | 12,500 |
| N-Acetylprocainamide                    | 12,500 |
| Chlordiazepoxide                        | 12,500 |
| MARIJUANA (THC 12)                      |        |
| 11-nor- $\Delta^9$ -THC-9 COOH          | 12     |
| Cannabinol                              | 31,500 |
| 11-nor- $\Delta^8$ -THC-9 COOH          | 2      |

| BENZODIAZEPINES (BZO 10)              |       |
|---------------------------------------|-------|
| Oxazepam                              | 10    |
| Alprazolam                            | 6     |
| Bromazepam                            | 12    |
| Chlordiazepoxide                      | 12    |
| Clobazam                              | 6     |
| Clorazepate                           | 25    |
| Delorazepam                           | 25    |
| Desalkylflurazepam                    | 25    |
| Diazepam                              | 3     |
| Estazolam                             | 3     |
| Flunitrazepam                         | 100   |
| $\alpha$ -Hydroxyalprazolam           | 200   |
| ( $\pm$ )-Lorazepam                   | 200   |
| Midazolam                             | 25    |
| Nitrazepam                            | 12    |
| Norchlordiazepoxide                   | 200   |
| Nordiazepam                           | 25    |
| Temazepam                             | 6     |
| Triazolam                             | 25    |
| l-Phenylephrine                       | 4,000 |
| Procaine                              | 2,000 |
| (1R,2S)-(-)-Ephedrine                 | 400   |
| 1-Ephedrine                           | 400   |
| Mephentermine                         | 800   |
| (-)-Deoxyephedrine, L-Methamphetamine | 3,000 |
| Ephedrine                             | 800   |
| MORPHINE (MOP 15)                     |       |
| Morphine                              | 15    |

|                                      |        |
|--------------------------------------|--------|
| Δ <sup>8</sup> -THC                  | 6,000  |
| Δ <sup>9</sup> -THC                  | 20,000 |
| <b>METHADONE (MTD 30)</b>            |        |
| Methadone                            | 30     |
| Doxylamine                           | 50,00  |
| Estrone-3-sulfate                    | 50,00  |
| Phencyclidine                        | 50,00  |
| <b>METHAMPHETAMINE (MET 50)</b>      |        |
| d-Methamphetamine                    | 50     |
| Fenfluramine                         | 60,000 |
| p-Hydroxymethamphetamine             | 400    |
| Methoxyphenamine                     | 25,000 |
| 3,4-Methylenedioxyamphetamine (MDMA) | 50     |
| 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  |
| <b>PROPOXYPHENE (PPX 50)</b>         |        |
| Propoxyphene (PPX)                   | 50     |
| D-Norpropoxyphene                    | 200    |

|                              |        |
|------------------------------|--------|
| Codeine                      | 15     |
| Ethylmorphine                | 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     |
| <b>OPIATE (OPI 40)</b>       |        |
| Morphine                     | 40     |
| Codeine                      | 10     |
| Ethylmorphine                | 24     |
| Hydromorphone                | 100    |
| Hydrocodone                  | 100    |
| Nalorphine                   | 10,000 |
| Oxymorphone                  | 25,000 |
| Thebaine                     | 1,500  |
| Diacetylmorphine (Heroin)    | 50     |
| 6-Monoacetylmorphine (6-MAM) | 25     |
| Morphine                     | 40     |

### Cross-Reactivity

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

### Non Cross-Reacting Compounds

|                                 |                                 |
|---------------------------------|---------------------------------|
| Acetaminophen                   | Labelalol                       |
| Acetophenetidine                | Loperamide                      |
| Acetylsalicylic acid            | Meprobamate                     |
| Aminopyrine                     | Methylphenidate                 |
| Amoxicillin                     | Nalidixic acid                  |
| Ampicillin                      | Naproxen                        |
| Amirtryptiline                  | Niacinamide                     |
| Ascorbic acid                   | Nifedipine                      |
| Apomorphine                     | Nimesulide                      |
| Aspartame                       | Norethindrone                   |
| Atropine                        | Noscapine                       |
| Benzilic acid                   | d,l-Octopamine                  |
| Benzoic acid                    | Oxalic acid                     |
| Benzphetamine                   | Oxolinic acid                   |
| Caffeine                        | Oxymetazoline                   |
| Chloral hydrate                 | Papaverine                      |
| Chloramphenicol                 | Penicillin-G                    |
| Chlorothiazide                  | Pentazocine                     |
| d,l-Chloropheniramine           | Perphenazine                    |
| Chlorpromazine                  | Phenelzine                      |
| Chloroquine                     | Trans-2-phenylcyclo-propylamine |
| Cholesterol                     | Phentermine                     |
| Clonidine                       | Phenylpropanolamine             |
| Cortisone                       | Prednisolone                    |
| Creatinine                      | Phenolbarbital                  |
| Deoxycorticosterone             | Prednisone                      |
| Dextromethorphan                | d,l-Propranolol                 |
| Diclofenac                      | d-Pseudoephedrine               |
| Dicyclomine                     | Quinacrine                      |
| Diflunisal                      | Quinine                         |
| Digoxin                         | Quindine                        |
| Diphenhydramine                 | Ranitidine                      |
| β-Estradiol                     | Salicylic acid                  |
| Ethyl-p-aminobenzoate           | Sulfamethazine                  |
| l-Epinephrine                   | Sulindac                        |
| Erythromycin                    | Tetracycline                    |
| Fenoprofen                      | Tetrahydrocortisone3-acetate    |
| Furosemide                      | Tetrahydrocortisone             |
| Gentisic acid                   | 3 (β-d-glucuronide)             |
| Hemoglobin                      | Theophylline                    |
| Hydralazine                     | Thiamine                        |
| Hydrochlorothiazide             | Thioridazine                    |
| Hydrocortisone                  | d,l-Tyrosine                    |
| o-Hydroxyhippuric acid          | Tolbutamide                     |
| βHydroxynorephedrine            | Trazodone                       |
| 5-Hydroxytryptamine (Serotonin) | Triamterene                     |
| 3-Hydroxytyramine               | Trifluoperazine                 |
|                                 | Trimethoprim                    |

Ibuprofen  
Iproniazid  
(-)-Isoproterenol  
Isoxsuprine  
Ketoprofen

d,l-Tryptophan  
Tyramine  
Uric acid  
Verapamil  
Zomepirac

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Manufactured for:

**DTC**

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