# Alere™ ToxWipe™

Qualitative Detection of Drugs of Abuse in Human Saliva, and on surfaces or solids: Amphetamine, Opiates, Cocaine, Methamphetamine, MDMA, Benzodiazepines, and Marijuana (THC)

## INTENDED USE

**ToxWipe™** is a rapid lateral flow immunoassay for the qualitative detection of drugs of abuse in human saliva and on surfaces or solids.

Up to 7 commonly abused drugs and drug metabolites can be detected including Amphetamine, Opiates, Cocaine, Methamphetamine, MDMA, Benzodiazepines, and Marijuana (THC).

**ToxWipe™** Cut-off Concentrations:

| Test | Cut-off (ng/mL, ppb) |
|---|---|
| Amphetamine (AM) | 50 |
| Methamphetamine / MDMA (ME) | 50/100 |
| Cocaine (CO) | 20 |
| Opiates (OP) | 40 |
| Marijuana (TH) | 25 |
| Benzodiazepines (BZ) | 10 |

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.

**ToxWipe™ is for professional use only and not for medical diagnostic purposes.**

## SUMMARY

**ToxWipe™** is a preliminary onsite screening test for up to 7 commonly abused drugs and drug metabolites, including Amphetamine, Opiates, Cocaine, Methamphetamine, MDMA, Benzodiazepines, and Marijuana (THC). The test can detect drug in human saliva, and on surfaces or solids.

Drugs can be rapidly metabolized in the blood after consumption via different routes[1]. Detection of drugs or drug metabolites in body fluids, such as blood, urine, and saliva can reveal recent drug use[2].

Saliva testing is becoming increasingly popular for drug testing due to its non-invasive and convenient sample collection[3]. In recent years, different studies have indicated a close correlation between the concentration of drugs and their metabolites in blood samples and in saliva samples[4-5]. Saliva collection is performed by "face to face" collection and therefore prevents sample adulteration and eliminates privacy concerns. Saliva collection can be easily and repeatedly performed under a variety of circumstances.

Surface or solid testing for drugs of abuse provides preliminary results in minutes for forensic purposes.

**ToxWipe™** is designed for user-friendly onsite rapid drug testing using saliva, or surface/solid specimens. The innovative design of **ToxWipe™** allows users to test for drugs of abuse with minimal sample collection time.

## TEST PRINCIPLE

The **ToxWipe™** is an immunoassay based on the principle of competitive binding. Drugs which may be present in the specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, the specimen migrates by capillary action. For solid specimens, the buffer solution will carry the specimen once the collection pad is inserted into the auxiliary cap.

A drug, if present in the specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug 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 will saturate all the binding sites of the antibody and a colored line will not form in the test line region.

A drug-positive specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative specimen will generate a line in the test line region because there is no drug competition.

To serve as a procedural control, a colored line will appear at the control line region if the test has been performed properly.

## PRECAUTIONS

- **ToxWipe™** is for professional use only and not for medical diagnostic purposes.
- **ToxWipe™** is intended for testing human saliva and surface/solid specimens.
- For saliva testing, the donor must not eat or drink within 10 minutes before testing.
- When placing the collection pad in mouth for saliva collection, the donor must not chew any part of the tip. Do not place the collection pad in mouth for extended time (more than 3 minutes).
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests. Read the entire procedure carefully prior to testing.
- Handle all specimens as if they contain infectious agents. Follow established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens.
- Humidity and temperature can adversely affect results.
- This test is for single use. Used testing materials should be discarded in accordance with local regulations.

## STORAGE AND STABILITY

Store the original package at 2-30°C. Check the expiration date on the foil pouch. Do not use if the package is damaged or expired. The test device should remain in its original sealed pouch until use. Do not freeze.

## MATERIALS

**Each package contains:**

- **ToxWipe™** device
- Device cap with a sealed reagent chamber
- Desiccant pack

**Materials required but not provided:**

- Timer
- Gloves

## DIRECTIONS FOR USE

**Allow the ToxWipe™ device to come to room temperature [15-30°C (59-86°F)] prior to testing. For saliva testing, instruct the donor not to place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.**

**1.** Remove the test device from the sealed foil pouch.

**2.** Collect and add sample as follows:

**A.** For saliva:

Insert collection pad into mouth. Actively swab around the gums and tongue before placing the collection pad under tongue to aid specimen collection. When sufficient saliva has been collected to run the test at least one of the blue lines at the bottom of the display windows will disappear/wick up, and/or the collection pad will be visibly saturated with saliva. The saliva specimen should only touch the absorbent area. Do not swipe the test device at any point above the visible outer collection pad.

**B.** For surfaces/solids:

The operator must wear clean gloves. While holding the device, use index finger to press on the collection pad and swipe both sides of the tip against the suspected surface or solid.

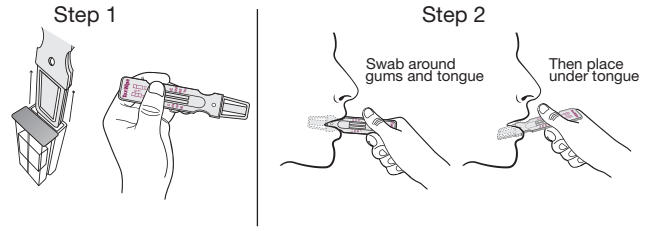
**Note:** In the collection of surface/solid specimens the blue lines will not disappear until after the tip is inserted into the cap.

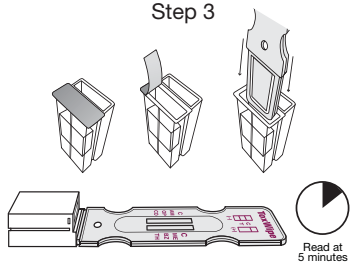
**3.** Peel the cover off of the sealed cavity of the reagent cap and place the collection pad of the test device all the way in. Place the test device on a flat surface and set a timer.

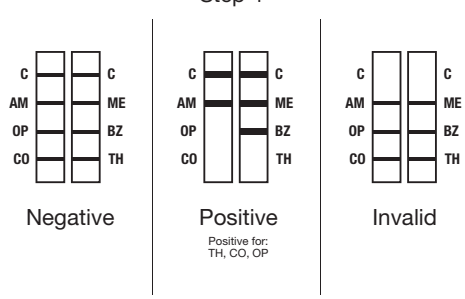
**4.** Read the test results at 5 -10 minutes. See illustration below.

If all lines are visible at 5 minutes then the test can be interpreted as negative and discarded. If all lines are not visible at 5 minutes then the test should be re-read at 10 minutes.

Do not interpret results after 10 minutes.



## INTERPRETATION OF TEST VALIDITY AND RESULTS

(Please refer to the previous illustration)

**NEGATIVE:* All test lines appear.** A colored line in the control region (C), and a colored line in the test region for specific drug indicate a negative result. This negative result indicates that the drug concentration is below the cut-off level for that specific drug.

***NOTE:** The shade of color in the test region will vary, but it should be considered negative whenever there is even a faint colored line.

**POSITIVE: A colored line in the control region (C) but no line in the test region regions for a specific drug indicates a positive result.** This positive result indicates that the drug concentration is above the cut-off level for that specific drug.

**INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.** Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot immediately and contact your supplier.

## TEST LIMITATIONS

1. **ToxWipe™** is a qualitative test only, and cannot determine the frequency of drug use or concentration of drugs or drug metabolites in the sample. The test is intended to distinguish a preliminary positive result from a negative result.
2. There is a possibility that technical or procedural errors as well as interfering substances may cause false results.
3. The test does not distinguish between drugs of abuse and certain medications.
4. A positive result indicates the presence of a drug only, and does not indicate or measure intoxication.
5. A negative result does not at any time rule out the presence of drugs in tested sample, as they may be present below the minimum detection level.
6. Under certain physiological or pathological conditions, such as waking from sleep in the early morning or dry mouth syndrome, saliva collection time may be prolonged.

## QUALITY CONTROL

The control line of the test device is a built-in quality control feature. The quality control test serves to confirm the testing procedure, liquid flow and general antibody-antigen binding are properly functional. This control line should appear regardless of the presence of drug or metabolite.

## PERFORMANCE CHARACTERISTICS

### Analytical Sensitivity

Analytical precision was evaluated by testing spiked saliva controls with 3 lots of product. Each lot was tested at concentration levels of negative, -50%, -25%, +25%, +50% and +100% of the cut-off level.

| Conc. Relative to Cut-off Level | AMP | | OPI | | COC | | MET | | BZO | | THC | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | - | + | - | + | - | + | - | + | - | + | - | + |
| 0% | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 |
| -50% | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 |
| -25% | 43 | 2 | 45 | 0 | 43 | 2 | 45 | 0 | 41 | 4 | 44 | 1 |
| +25% | 5 | 40 | 1 | 44 | 3 | 42 | 1 | 44 | 6 | 39 | 2 | 43 |
| +50% | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 |
| +100% | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 | 0 | 45 |

### Cross-Reactivity

Cross-reactivity was evaluated by testing saliva controls spiked with structurally similar compounds and/or various drugs and drug metabolites within the same class of drugs.

| COMPOUND | CONC. (ng/mL) | % CROSS REACTIVITY |
|---|---|---|
| **AMPHETAMINE** | | |
| d-Amphetamine | 50 | 100% |
| d,l-Amphetamine | 100 | 50% |
| R-Amphetamine | 2,000 | 2.5% |
| d-MDA | 150 | 33.3% |
| p-Methoxyamphetamine | 125 | 40% |
| Phentermine | 10,000 | 0% |
| Tyramine | 500 | 10% |
| | | |
| **BENZODIAZEPINES** | | |
| Oxazepam | 10 | 100% |
| Alprazolam | 10 | 100% |
| Bromazepam | 200 | 5% |
| Chlordiazepoxide | 10,000 | 0% |
| Clobazam | 80 | 12.5% |
| Diazepam | 20 | 50% |
| Flurazepam | 10,000 | 0% |
| Lorazepam | 1,200 | 0.8% |
| Lormetazepam | 200 | 5% |
| Midazolam | 10,000 | 0% |
| Nitrazepam | 8,000 | 0.1% |
| Nordiazepam | 20 | 50% |
| Temazepam | 50 | 20% |
| Triazolam | 10,000 | 0% |
| | | |
| **COCAINE** | | |
| Cocaine | 25 | 100% |
| Benzoylecgonine | 50 | 100% |
| Ecgonine | 2,500 | 1% |
| Methyl Ester | 12,500 | 0.2% |
| | | |
| **METHAMPHETAMINE/ MDMA** | | |
| Methamphetamine | 50 | 100% |
| d,l-Ephedrine | 250 | 20% |
| 1R, 2S, l-Ephedrine | 150 | 33.3% |
| p-Hydroxymethamphetamine | 950 | 5.3% |
| MDEA | 2,400 | 2.1% |
| MDMA | 100 | 50% |
| d,l-Methamphetamine | 150 | 33.3% |
| l-Methamphetamine | 10,000 | 0% |
| Methoxyphenamine | 300 | 16.7% |
| l-Amphetamine | 10,000 | 0% |
| | | |
| **OPIATES** | | |
| Morphine | 40 | 100% |
| 6-Acetylcodeine | 55 | 72.7% |
| 6-Acetylmorphine | 45 | 88.9% |
| Codeine | 40 | 100% |
| Dihydrocodeine | 30 | 133.3% |
| Ethyl morphine | 35 | 114.3% |
| Heroin | 55 | 72.7% |
| Hydrocodone | 36 | 111.1% |
| Hydromorphone | 40 | 100% |
| Nalorphine | 10,000 | 0% |
| Oxycodone | 2,300 | 1.7% |
| | | |
| **THC** | | |
| Δ9-Tetrahydrocannabinol | 25 | 100% |
| Cannabinol | 12.5 | 200% |
| Δ-8-Tetrahydrocannabinol | 16 | 160% |
| 11-nor-Δ9-THC-COOH | 16 | 160% |
| 11-Hydroxy-Δ9-THC | 12.5 | 200% |

### Interference

Interference was evaluated by testing oral fluid controls spiked with endogenous substances, structurally unrelated compounds, and other potential substances that may be present in saliva. The following compounds demonstrated no false positive results on the **ToxWipe™** when tested with concentrations up to 10,000 ng/ml.

Acetaminophen
Acetylsalicylic Acid
Amoxillin
Ampicillin
l-Ascorbic Acid
Bilirubin
Caffeine
l-Cotinine
Diclofenac
Erythromycin
Estradiol
3-Hydroxybutyric Acid
Ibuprofen
Ketamine
Loperamide
Naproxen
Penicillin
Phencyclidine
Prednisolone
Sulfathiazole
Tetracycline
Thiamine

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