Oranoxis

ToxWipe™-Oral +

Intended Use

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

ToxWipe™ is a rapid lateral flow immunoassay for the qualitative detection of drugs of abuse in human saliva.

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

ToxWipe™ cut-off concentrations:

Test	Cut-Off
Amphetamine (AM)	50
Methamphetamine (ME)	50
Cocaine (CO)	20
Opiates (OP)	40
Benzodiazepines (BZ)	10
Marijuana (TH)	15

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.

Materials

Each package contains:

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

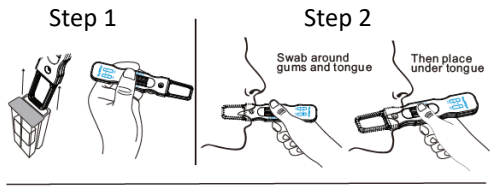
Materials recommended but not provided:

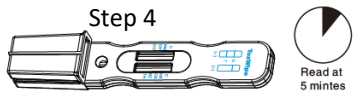
- Timer
- Gloves

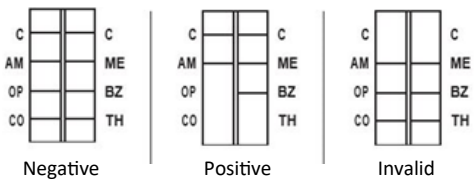
Directions for Use

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

1. Remove the test device from the sealed foil pouch.
2. Collect and add sample as follows:
   Insert collection pad into mouth. Actively swab around the gums and tongue for stimulation before placing the collection pad under tongue to aid specimen collection. When sufficient saliva has been collected to run the test both of the blue lines at the bottom of the display windows will disappear/wick up. The saliva specimen should only touch the absorbent area. Do not swipe the test device at any point above the visible outer collection pad.
3. Once both blue indicator lines are wet/wicking use the corner of the device tip to puncture the middle of the cover of the sealed cavity (see Step 3 illustration below) and push the collection pad of the test device all the way in. Place the test device on a flat surface and set a timer for 10 minutes.
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 any results read positive at 5 minutes, then final results should be read at 10 minutes. Do not interpret results after 10 minutes.







Interpretation of 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 and contact your supplier.

Precautions

- ToxWipe™ is for professional use only and not for medical diagnostic purposes.
- ToxWipe™ is intended for testing human saliva.
- "Dry Mouth" or "Dry Mouth Syndrome," certain medications, or certain diseases may affect results. Please stimulate oral fluid 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 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 punctured or 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, punctured, or expired. The test device should remain in its original sealed pouch until use. Do not freeze.

Summary

ToxWipe™ is a preliminary onsite screening test for up to 7 commonly abused drugs and drug metabolites, including Amphetamine, Opiates, Cocaine, Methamphetamine, Benzodiazepines, and Marijuana.

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

Saliva testing is becoming increasingly popular for drug testing due to its non-invasive and convenient sample collection. 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. 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.

Test Limitations

- ToxWipe™ is a qualitative test only, and cannot determine the frequency of drug use or concentration of drugs or metabolites in the sample. The test is intended to distinguish a preliminary positive result from a negative result.
- ToxWipe™ doesn't distinguish between drugs of abuse and certain medications.
- A positive result indicates the presence of a drug only, and does not indicate or measure intoxication.
- 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.
- Under certain physiological or pathological conditions 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 confirms 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.

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

Performance Characteristics

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
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%
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		
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%

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	43	2
+25%	5	40	1	44	3	42	1	44	6	39	3	42
+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

Manufactured by Oranoxis Inc.
7438 Trade Street, San Diego, CA 92121 USA

For more info, please visit:
www.Oranoxis.com
1-800-559-2490

Revision 1.1