

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE

The **ORAL-VIEW™** Saliva Multi-Drug of Abuse Test is a one-step rapid qualitative immunoassay for the screening of potential abuse of one or more drugs in human oral fluid at the following concentrations:

Abbreviation	Test	Cutoff	Detection Time
AMP	Amphetamine	50 ng/mL	10 min – 72 hours
BZD	Benzodiazepines	20 ng/mL	10 min – 72 hours
COC	Cocaine	20 ng/mL	10 min – 24 hours
OPI	Morphine	40 ng/mL	1 hour – 72 hours
THC	Marijuana/Hashish	12 ng/mL	1 hour – 14 hours

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or high performance liquid chromatography (HPLC) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY

Amphetamine (AMP)

Amphetamines are central nervous system stimulating drugs. They may induce alertness, wakefulness, increased energy, reduced hunger and overall feeling of well being. Overdose and extended usage of amphetamines may lead to substance abuse, which may cause severe and/or permanent damage to the human nervous system.

Benzodiazepines (BZD)

Benzodiazepines, including Alprazolam, Diazepam, Lorazepam, Triazolam, Chlordiazepoxide, Flurazepam and Temazepam are sedative, hypnotic and anti-anxiety drugs commonly being used as oral tranquilizers. Benzodiazepines have a low potential for physical or psychological dependence. However, as with other central nervous system stimulating drugs, they may induce drowsiness and muscle relaxation. Chronic abuse of benzodiazepines may result in intoxication, similar to drunken behavior. Overdose and extended usage of benzodiazepines may lead to coma and possibly death. The members of the Benzodiazepine family are absorbed at different rates and their effects may vary with the absorption rate.

Cocaine (COC)

Cocaine is a nervous system stimulant that can be addictive. Physical effects of cocaine use include constricted peripheral blood vessels, dilated pupils, and increased body temperature, heart rate, and blood pressure. Some cocaine users report feelings of restlessness, irritability, and anxiety, both while using and between periods of use. High doses of cocaine and/or prolonged use can trigger paranoia. Smoking crack cocaine can produce particularly aggressive paranoid behavior in users (long-term effects). Prolonged cocaine snorting can result in ulceration of the mucous membrane of the nose and can damage the nasal septum enough to cause it to collapse. Cocaine-related deaths are often a result of cardiac arrest or seizures followed by respiratory arrest.

Morphine (OPI)

Morphine is a popular marketed drug (Serax) for treatment of moderate to severe pain. It is also a common metabolite of opiates [morphine, codeine (methyl-morphine), and heroin (semi-synthetic derivatives of morphine)]. The opiates are administered by smoking, intravenous injection, intramuscular injection or oral ingestion. Adverse or toxic effects of opiates usage include pupillary constriction, constipation, urinary retention, nausea, vomiting, hypothermia, drowsiness, dizziness, apathy, confusion, respiratory depression, hypotension, cold and clammy skin, coma, and pulmonary edema. Death may occur following an over-dosage.

Marijuana (THC)

Tetrahydrocannabinols (THC, Δ-9-THC) are the most active of the principal constituents, as well as the major metabolites of cannabinoids such as marijuana and hashish. Cannabinoids have been used as central nervous system depressants. Overdose and extended usage of cannabinoids may lead to substance abuse, which may cause severe and/or permanent damage to the human nervous system.

PRINCIPLE OF THE PROCEDURE

The **ORAL-VIEW™** Saliva Multi-Drug of Abuse Test is a one-step lateral flow chromatographic immunoassay based on the principle of competition for limited antibody binding sites between the drug in the sample and a drug-protein conjugate immobilized on a porous membrane support.

During testing, the oral fluid migrates to the testing area of the membrane by capillary action, mobilizing the colored antibody conjugates. The antibody conjugates then move along the membrane to the test area. In the absence of drug or if drug concentrations are below the cutoff limit in the oral fluid, the colored conjugates attach to the respective drug antigen immobilized in the test line region, forming a burgundy-colored band (T line). If drug is present in the oral fluid, the drug competes for the limited antibody binding sites. If the drug concentration is at or above the cutoff limit, the drug will saturate all the binding sites of the antibody, preventing the attachment of the colored conjugates to the antigen in the test line area of the membrane. Therefore no colored line will form.

The control line (C line) serves as an internal quality control of the system. It should always appear as a burgundy-colored band regardless of the presence of the drug.

REAGENTS AND MATERIALS SUPPLIED

- 1 Individually pouched multi-dug of abuse test device with cap
- 1 Package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

PRECAUTIONS

- The instructions must be followed exactly to obtain accurate results.
- Do not open the sealed pouch, unless ready to conduct the assay.
- Do not use expired devices.
- Do not moisten nitrocellulose membrane with samples.
- Dispose of used device according to local regulations.

STORAGE AND STABILITY

- Store the product in the sealed pouch at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.
- Do not freeze and / or expose this kit to temperatures over 30°C (86°F).

SPECIMEN COLLECTION AND TESTING

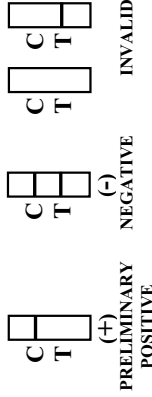
Do not freeze the kit or expose to 30°C
15°C

The test device must be equilibrated to room temperature before testing.

1. Bring the sealed pouch to **room temperature before opening**. Remove the test device from the pouch and use it as soon as possible.
2. **Remove cap and insert the collection pad end of the device into the subject's mouth**, wiping the pad in the subject's mouth for about 1-3 minutes until the collection pad is completely saturated. **Keep the opposite end of the device angled downward** to ensure good flow (also refer to the procedure card), and **do not pull on or chew the collection pad**.
3. When color appears in the result window **remove the device from the subject's mouth** and replace the cap onto the collection pad end of the device. Lay the device on a flat surface.
4. **Start timing once the C line is visible in the test window. Read results 5-7 minutes after the C line appears.**

INTERPRETATION OF RESULTS

IMPORTANT: Do not read test results after seven (7) minutes following appearance of the C line. The T line should always be interpreted independently of the C line. Do not compare color intensity of one test line to another.



Preliminary Positive:

If a colored line appears in the control line region (C), but there is no line in the test line region (T), the result indicates a positive result for that drug.

Note: Samples with preliminary positive results should be confirmed with a more specific method before positive determinations are made.

Negative:

A colored line in the control line region (C) and another line in the test line region (T) indicate that the corresponding drug is not present, or the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

Note: A very faint T line should be considered negative.

Invalid:

If no C line develops, the result is invalid. Insufficient specimen volume or incorrect procedural technique 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, stop the test and contact your distributor.

QUALITY CONTROL

Built-in Control Features:

This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If no C line forms, the test is considered invalid. Review the procedure and repeat testing with a new device.

External Quality Control:

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. Users should always follow appropriate local guidelines concerning the running of external quality controls.

LIMITATIONS

- This kit is for professional *in vitro* diagnostic use only.
- Results obtained by this device provide only a preliminary, qualitative analytical test result. A more specific chemical method must be used to obtain a confirmed analytical result.
- This product is designed for testing human oral fluid only.
- 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.

EXPECTED VALUES

This test is capable of detecting the specific drug and/or drug metabolite in human oral fluid at or above its specific cutoff concentration indicated in the Intended Use section.

PERFORMANCE CHARACTERISTICS

Accuracy

A comparison study was performed at an academy of science. Ninety (90) samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested with the multi-drug of abuse saliva device and compared to HPLC/MS results. The test results are grouped into: below 50% cutoff (Negative), between 50% cutoff and cutoff, between cutoff and 150% cutoff and above 150% cutoff (Positive). Seven (7) discrepancies were observed at the level between cutoff and 150% cutoff.

Overall, this device agrees with the results from the selected analytical method at more than 95% for each analyte. The test results are tabulated as follows:

AMP	Cutoff: 50 ng/mL		Total	Agreement
	Negative (<50%)	50%-cutoff		
HPLC/MS (ng/mL)	0	30	30	100%
Cutoff: 150%	8	2*	10	80%
Positive (>150%)	40	0	40	100%
Total	48	42	90	97.7%

BZD	Cutoff: 20 ng/mL		Total	Agreement
	Negative (<50%)	50%-cutoff		
HPLC/MS (ng/mL)	0	10	10	100%
Cutoff: 150%	9	1*	10	90%
Positive (>150%)	40	0	40	100%
Total	49	41	90	98.8%

COC	Cutoff: 20 ng/mL		Total	Agreement
	Negative (<50%)	50%-cutoff		
HPLC/MS (ng/mL)	0	10	10	100%
Cutoff: 150%	8	2*	10	80%
Positive (>150%)	40	0	40	100%
Total	48	42	90	97.7%

OPI	Cutoff: 40 ng/mL		Total	Agreement
	Negative (<50%)	50%-cutoff		
HPLC/MS (ng/mL)	0	10	10	100%
Cutoff: 150%	10	0	10	100%
Positive (>150%)	40	0	40	100%
Total	50	40	90	100%

THC	Cutoff: 12 ng/mL		Total	Agreement
	Negative (<50%)	50%-cutoff		
HPLC/MS (ng/mL)	0	10	10	100%
Cutoff: 150%	8	2*	10	80%
Positive (>150%)	40	0	40	100%
Total	48	42	90	97.7%

* indicates discrepancy.

Reproducibility:

The reproducibility of the test was determined by replicate assays of three product development lots with four levels of samples: negative, 50% cutoff, 150% cutoff, positive. A total of two hundred and sixteen devices were tested for three consecutive days, six replicates per day. The results indicate over 97% agreement with the replicates within each lot and for inter-lot variation.

Cross Reactivity:

The cross reactivity of the test was evaluated by spiking drug free samples with structurally related compounds. Compounds producing positive responses are listed below:

Drug	Compound	Concentration (ng/mL)
AMP	d-Amphetamine	50
	d-l-Amphetamine	100
	p-Hydroxymethamphetamine	20,000
BZD	l-Methamphetamine	50,000
	3,4-Methylenedioxymphetamine (MDA)	100
	Diazepam	20
COC	Oxazepam	20
	Nitrazepam	20
	Flurazepam	5,000
OPI	Clobazam	30
	Bromazepam	20
	Alprazolam	20
THC	Lorazepam	20
	Cocaine	20
	Codeine	30
THC	Benzoylecgonine hydrate	40
	Morphine 3-β-D-glucuronide	100
	Hydromorphone	180
THC	Oxycodone	3,000
	Hydrocodone	100
	Diaceylmorphine (Heroin)	100
THC	(-)-11-nor-Δ ⁸ -THC-9-COOH	12
	11-Hydroxy-Δ ⁸ -THC	300
	11-nor-Δ ⁸ -THC-9-COOH	12

Interference:

The following commonly used analytes were evaluated in both drug free saliva pools and in pools spiked with the cutoff level of each substance. The tables below list the concentrations at which the substances and analytes do not interfere with the test results:

Substance	Concentration	Substance	Concentration
Acetaminophen	100 µg/mL	Isosuprine	100 µg/mL
Acetylsalicylic acid	100 µg/mL	MBDB	100 µg/mL
Amitriptyline	100 µg/mL	MDEA	10 µg/mL
Amobarbital	100 µg/mL	MDMA	1 µg/mL
Amoxicillin	100 µg/mL	Meprobamate	1 µg/mL
Aspirin	100 µg/mL	Methadone	1,000 µg/mL
Benzene acid	100 µg/mL	Methanol	100 µg/mL
Buprenorphine	100 µg/mL	Methanol	100 µg/mL
Buabarbital	100 µg/mL	Penicillin-G	100 µg/mL
Buabarbital	100 µg/mL	Phenothiazine	100 µg/mL
Caffeine	100 µg/mL	Salicylic acid	100 µg/mL
Cortisone	100 µg/mL	EDDP	100 µg/mL
Ethanol	100 µg/mL	Genistic acid	100 µg/mL
Hydroxybutyric acid	1,000 µg/mL	Ecgonine methyl ester	10 µg/mL
Imipramine	1 µg/mL		

Biological Analytes	Concentration	Biological Analytes	Concentration
Albumin	2,000 µg/mL	Hemoglobin	100 µg/mL
Bilirubin	100 µg/mL	Uric acid	100 µg/mL
Creatine	100 µg/mL	Vitamin C	100 µg/mL
Glucose	200 µg/mL	[L-Ascorbic acid]	

REFERENCES

- Jenkins AJ, Goldberger BA, editors. On-Site Drug Testing. Totowa (NJ): Humana Press; 2002.
- Baselt RC, Cravey RH, editors. Disposition of Toxic Drugs and Chemicals in Man. 4th ed. Davis (CA): Biomedical Publications; 1995.
- National Institute on Drug Abuse. Mandatory guidelines for federal workplace drug testing programs. Fed Regist 1988 Apr 11; 53(69): 11970-11989.
- Wilson J. Abused Drugs II: A Laboratory Pocket Guide. Washington DC: AACCPress; 1994.
- Gilman AG, Rall TW, Nies AS, Taylor P, editors. Goodman and Gilman's: The Pharmacological Basis of Therapeutics, 8th ed. New York: Pergamon Press; 1990.

Temperature limitation

Batch/Lot code

Manufacturer

Contains sufficient for <n > tests

Do not reuse

Caution, consult accompanying documents

Use by
YYYY-MM

In vitro diagnostic
medical device

Catalog number

Consult
instructions for use

CE Mark



REF 4210

Distributed by Labstix Diagnostics Pty Ltd
P O Box 904520, Faerie Glen, 0043
Tel: (013) 947 8049 / Fax: 086 669 7760
email: info@labstix.co.za
www.labstix.co.za

NOT FOR SALE IN USA OR CANADA