

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
AMP	d-Amphetamine	50 ng/mL
	d-l-Amphetamine	100 ng/mL
	p-Hydroxymethamphetamine	20,000 ng/mL
	l-Methamphetamine	50,000 ng/mL
OPI	3,4-Methylenedioxyamphetamine (MDA)	100 ng/mL
	Codeine	40 ng/mL
	Morphine 3-β-D-glucuronide	100 ng/mL
	Hydromorphone	180 ng/mL
	Oxycodone	3,000 ng/mL
	Hydrocodone	100 ng/mL
THC	Diacetylmorphine (Heroin)	100 ng/mL
	(-)-11-nor-Δ ⁹ -THC-9-COOH	12 ng/mL
	11-Hydroxy-Δ ⁹ -THC	300 ng/mL
COC	11-nor-Δ ⁹ -THC-9-COOH	12 ng/mL
	Cocaine	20 ng/mL
	Benzoyllecgonine hydrate	30 ng/mL
BZD	Ecgonine Methylester	10,000 ng/mL
	Diazepam	20 ng/mL
	Oxazepam	20 ng/mL
	Nitrazepam	20 ng/mL
	Flurazepam	5,000 ng/mL
	Clobazam	30 ng/mL
	Bromazepam	20 ng/mL
	Alprazolam	20 ng/mL
MET/XTC	Lormetazepam	20 ng/mL
	(+)-Methamphetamine hydrochloride	50 ng/mL
	l-Amphetamine	100 ng/mL
PCP	3,4-Methylenedioxymethamphetamine	50 ng/mL
	Phencyclidine	10 ng/mL
MTD	Tetrahydrozoline	150,000 ng/mL
	(+)-Methadone hydrochloride	20 ng/mL
	Doxylamine	50,000 ng/mL

Interference









The following common substances were evaluated in both drug free saliva pools and in pools spiked at the cutoff level of each substance. The following table lists the concentrations at which the analytes do not interfere with the test results:

Substance	Concentration	Substance	Concentration
Acetaminophen	100 µg/mL	Cortisone	100 µg/mL
Acetylsalicylic acid	100 µg/mL	Ethanol	100 µg/mL
Amitriptyline	100 µg/mL	Hydroxybutyric acid	1,000 µg/mL
Amobarbital	100 µg/mL	Imipramine	1 µg/mL
Ampicillin	100 µg/mL	Meperidine	1 µg/mL
Aspirin	100 µg/mL	Methadol	100 µg/mL
Benzoic acid	100 µg/mL	Methanol	100 µg/mL
Buprenorphine	100 µg/mL	Penicillin-G	100 µg/mL
Butabarbital	100 µg/mL	Phenothiazine	100 µg/mL
Butabital	100 µg/mL	Salicylic acid	100 µg/mL
Caffeine	100 µg/mL	Gentisic acid	100 µg/mL

Substance	Concentration	Substance	Concentration
Albumin	2,000 µg/mL	Hemoglobin	100 µg/mL
Bilirubin	100 µg/mL	Uric acid	100 µg/mL
Creatine	100 µg/mL	l-Ascorbic acid (Vitamin C)	100 µg/mL
Glucose	200 µg/mL		

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: AACC Press; 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.
- Daniel Malamud, R.Sam Niedbala, editors. Oral-Based Diagnostics. Annals of The New York Academy of Science, V1098, 2007.

 Temperature limitation	 Use by YYYY-MM
 Batch/Lot code	 Catalog number
 Manufacturer	 Consult instructions for use
 Contains sufficient for <n> tests	 Do not reuse

Manufactured for:
Confirm Biosciences, Inc.
SAN DIEGO, CA 92121 – USA
MADE IN USA

One Step Assay Rapid Visual Results

For Forensic or Investigational Use Only. This product is NOT for At Home or Over-the-Counter use. This product is NOT for use in any medical diagnosis or treatment in the United States

INTENDED USE

The ORAL-VIEW™ Saliva Multi-Drug of Abuse Test is a one-step rapid qualitative immunoassay for screening 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 hrs
BZD	Benzodiazepines	20 ng/mL	10 min – 72 hrs
COC	Cocaine	20 ng/mL	10 min – 24 hrs
OPI	Morphine	40 ng/mL	1 hr – 72 hrs
PCP	Phencyclidine	10 ng/mL	1 hr – 72 hrs
MET	Methamphetamine and Ecstasy	50 ng/mL	10 min – 72 hrs
MTD	Methadone	20 ng/mL	1hr-24 hrs
THC	Marijuana/Hashish	12 ng/mL	1 hr – 14 hrs

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 used as oral tranquilizers. Benzodiazepines have a low potential for physical or psychological dependence. However, the same as other central nervous system stimulating drugs, they may induce drowsiness and muscle relaxation. Chronic abuse of benzodiazepine may result in intoxication, similar to drunken behavior. Overdose and extended usage of benzodiazepines may lead to coma and possibly death. Benzodiazepines are absorbed at different rates and their effects may vary with the absorption rate.

Methamphetamine (MET) and Ecstasy

Methamphetamine overdose can cause restlessness, confusion, anxiety, hallucinations, cardiac arrhythmias, hypertension, circulatory collapse, convulsions, and coma. It has been implicated in fatal poisonings following both intravenous and oral administration. Chronic abusers may develop paranoid psychosis. Typically administered by oral, nasal insufflation, or intravenous injection. MET is utilized in the treatment of obesity. Ecstasy (Methylenedioxyamphetamine or MDMA) is a stimulant and hallucinogen structurally related to Methamphetamine. MDMA was once used for psychotherapy and is now a Schedule 1 drug in the US (no approved medical use).

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 use 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 frequently prescribed drug (under the trade name 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)]. Opiates are administered either 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 over-dosage.

Marijuana (THC)

Tetrahydrocannabinols (THC, Δ⁹-THC) are the most active of the principal constituents of cannabinoids such as marijuana and hashish, as well as the major metabolites. 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.

Phencyclidine (PCP)

PCP is a dissociative anesthetic reported in the 1950s. It is illicitly marketed under a number of street names including Angel Dust, Supergrass, Killer Weed. Among PCP's least side effects are delirium, visual disturbances and hallucinations and, occasionally, violence. PCP is well absorbed and readily penetrates the central nervous system after intravenous, smoked, intranasal, oral, and percutaneous administration. The plasma elimination half life is 7-50 h in normal volunteers. PCP has been measured by radioimmunoassay in oral fluid and serum specimens of emergency room patients suspected of PCP intoxication.

Methadone (MTD)

Methadone is a long-acting opioid μ-receptor agonist with pharmacological properties similar to those of morphine. Methadone is available as an oral concentrate and dispensable tablets for relief of chronic pain, treatment of opioid abstinence syndromes, and treatment of heroin dependence. Methadone appears rapidly in oral fluid and correlated with plasma concentrations.

PRINCIPLE OF THE PROCEDURE

The 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, 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 the drug concentration in oral fluid is below the cutoff limit, the colored conjugates attach to the respective drug antigen immobilized in the test line region, forming a colored band (T line). If drug is present in oral fluid, the drug competes for 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. It should always appear as a colored band regardless of the presence of the drug.

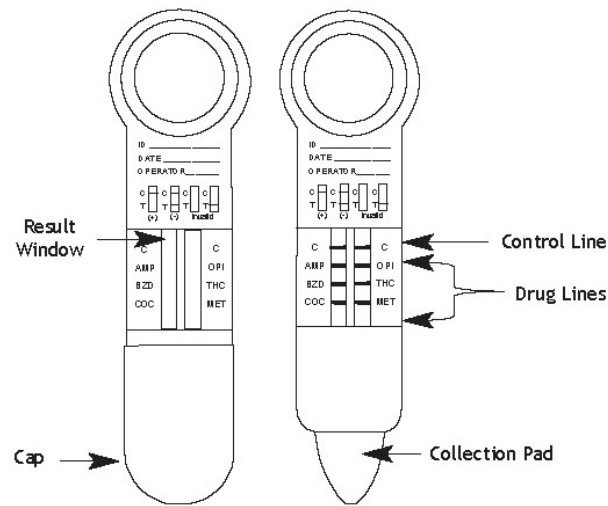
REAGENTS AND MATERIALS SUPPLIED

- 25 Individually pouched test devices with caps
- 1 Package Insert (Instructions for Use)
- 1 Procedure Card (Multilingual)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

TEST FORMAT



Test device pictures shown here, capped and uncapped to expose collection pad.

PRECAUTIONS

- The instructions must be followed exactly to obtain accurate results.
- Do not open the sealed pouch unless ready to perform the test.
- Do not use expired devices.
- Do not allow oral fluid specimens to contact the result window.
- Always wear gloves when testing.
- Dispose of used devices according to local regulations.

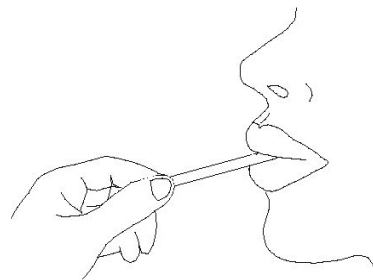
STORAGE AND STABILITY

- 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 the kit or expose to temperatures over 30°C (86°F).

SPECIMEN COLLECTION AND TESTING

IMPORTANT: Test devices must be at room temperature (15-30°C) 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. **Insert the collection pad end of the device into the subject's mouth. Keep the opposite end of the device angled downward** to ensure good flow (also refer to the procedure card),



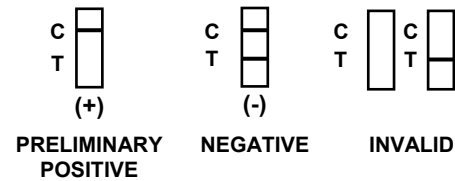
3. **Instruct the subject to move the collection pad from top to bottom of the tongue and back again filling the collection pad with saliva.** Keep the pad in the subject's mouth for about **1-3 minutes** until the collection pad is completely saturated. **Do not pull on or chew the collection pad.**

4. When migration of saliva or any pink/burgundy 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. Total time from the start of the test to the appearance of the C line depends on the saliva production and the viscosity of the saliva of the individual.

5. **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 line intensities between tests.



Preliminary Positive

A colored line in the control line region (C) with **no** line in the test line region (T) indicates a preliminary positive result for that drug.

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 respective drug is not present, or that the drug concentration in the oral fluid specimen is below the designated cutoff level for that drug.

Do not compare color intensity of one test line to another. Faint T lines should be considered negative results.

Invalid

If no C line develops, the result is invalid. 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, stop testing and contact your local distributor.

QUALITY CONTROL

Built-in Control:

This test contains a built-in control feature. 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 result 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 product is for forensic or investigational use only.
- This product is for testing human oral fluid only.
- Results obtained by this device provide only a preliminary, qualitative analytical test result. A more specific alternate oral fluid method must be used to obtain a confirmed analytical result.
- A negative result may not necessarily indicate a drug-free specimen. Drugs may be present in the specimen below the cut-off levels of the test.

EXPECTED VALUES

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

PERFORMANCE CHARACTERISTICS

Accuracy

Three hundred (300) spiked saliva samples were blind labeled and tested for each analyte (drug or drug metabolite). Each sample was tested with one test device. The test results were grouped into: below 50% cutoff (Negative), between 50% cutoff and cutoff, between cutoff and 150% cutoff, and above 150% cutoff (Positive). Twenty-six (26) discrepancies were observed at 50% cutoff to cutoff level. Twenty (20) discrepancies were observed at the cutoff to 150% cutoff level.

The test results are tabulated as follows:

AMP		Cutoff: 50 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	3*	27	30	90%
	Cutoff-150%	28	2*	30	93.3%
	Positive (>150%)	30	0	30	100%
Total		61	239	300	98.3%

BZD		Cutoff: 20 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	1*	29	30	96.7%
	Cutoff-150%	26	4*	30	86.7%
	Positive (>150%)	30	0	30	100%
Total		57	243	300	98.3%

COC		Cutoff: 20 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	3*	27	30	90%
	Cutoff-150%	29	1*	30	96.7%
	Positive (>150%)	30	0	30	100%
Total		62	238	300	98.7%

OPI		Cutoff: 40 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	4*	26	30	86.7%
	Cutoff-150%	30	0	30	100%
	Positive (>150%)	30	0	30	100%
Total		64	236	300	98.7%

PCP		Cutoff: 10 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	2*	28	30	93.3%
	Cutoff-150%	27	3*	30	90%
	Positive (>150%)	30	0	30	100%
Total		59	241	300	98.3%

XTC		Cutoff: 50 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	3*	27	30	90%
	Cutoff-150%	29	1*	30	96.7%
	Positive (>150%)	30	0	30	100%
Total		62	238	300	98.7%

MET		Cutoff: 50 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	5*	25	30	83.3%
	Cutoff-150%	29	1*	30	96.7%
	Positive (>150%)	30	0	30	100%
Total		64	236	300	98%

MTD		Cutoff: 20 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	0	30	30	100%
	Cutoff-150%	24	6*	30	80%
	Positive (>150%)	30	0	30	100%
Total		54	246	300	98%

THC		Cutoff: 12 ng/mL		Total	Agreement
		Positive	Negative		
Concentration range	Negative (<50%)	0	210	210	100%
	50%-cutoff	5*	25	30	83.3%
	Cutoff-150%	28	2*	30	93.3%
	Positive (>150%)	30	0	30	100%
Total		63	237	300	97.7%

* indicates discrepancy.

A consumer site study was also conducted with 300 blind labeled specimen samples. Three different technicians each conducted 100 tests and interpreted the results. The results of the study are summarized below. All of the 40 incorrect results were at drug concentrations at 50% ~ 150% of the cut offs. 19 positive samples were read as negative. 21 negative samples were read as positive.

Drug	Cutoff Conc. (ng/ml)	# Test	Result Interpretation		Overall
			Correct	Incorrect	
AMP	50	300	296	4	98.7%
BZD	20	300	295	5	98.3%
COC	20	300	297	3	99.0%
OPI	40	300	296	4	98.7%
PCP	10	300	295	5	98.3%
MET	50	300	296	4	98.7%
XTC	50	300	296	4	98.7%
MTD	20	300	294	6	98.0%
THC	12	300	295	5	98.3%

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 and positive. A total of two hundred and sixteen devices were tested for three consecutive days, six replicates per day. The results indicate greater than 97% precision for the replicates within each lot and for inter-lot variation.