salivaconfirm oral fluid multi-drug screening kit Oral Fluid Multi-Drug Screening Kit (US)

One Step Assay
Rapid Visual Results
For Forensic or Investigational use Only

INTENDED USE

The Salivaconfirm Oral Fluid Multi-Drug Screening Kit 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
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.

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, Δ^9-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.

PRINCIPLE OF THE PROCEDURE

The Salivaconfirm Oral Fluid Multi-Drug Screening Kit 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.

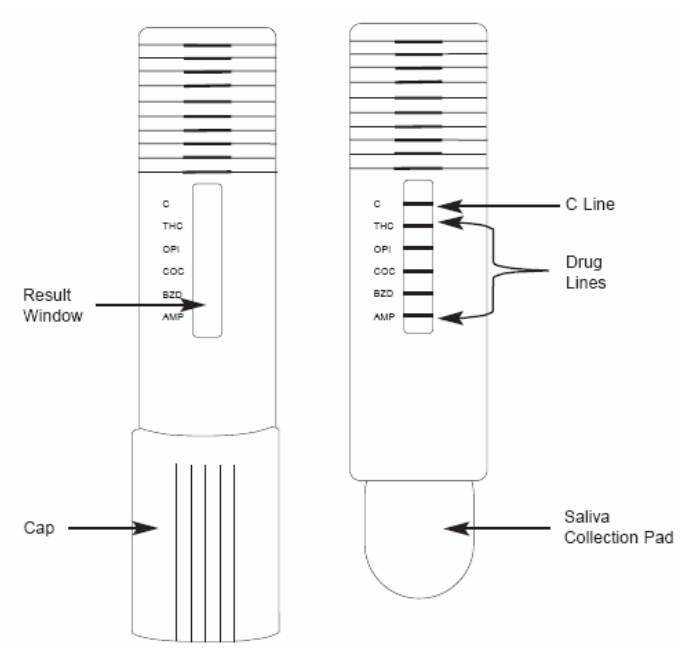
REAGENTS AND MATERIALS SUPPLIED

- 25 Individually pouched test devices with caps
- 1 Package insert (instructions for use)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

TEST FORMAT



Test device shown 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).

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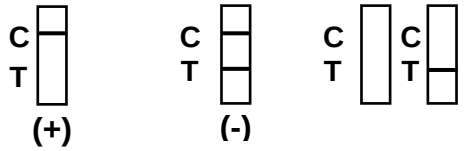
SPECIMEN COLLECTION AND TESTING

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 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 line intensities between tests.



PRELIMINARY POSITIVE | **NEGATIVE** | **INVALID**

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.

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

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 test device, and the results were compared to HPLC/MS results. 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). Seven (7) discrepancies were observed at the cutoff to 150% cutoff level.

Overall, this device exhibits greater than 95% agreement with the HPLC/MS results. The test results are tabulated as follows:

AMP		Cutoff: 50 ng/mL		Total	Agreement
		Positive	Negative		
HPLC/MS	Negative (<50%)	0	30	30	100%
	50%-cutoff	0	10	10	100%
	Cutoff-150%	8	2*	10	80%
	Positive (>150%)	40	0	40	100%
Total		48	42	90	97.8%

BZD		Cutoff: 20 ng/mL		Total	Agreement
		Positive	Negative		
HPLC/MS	Negative (<50%)	0	30	30	100%
	50%-cutoff	0	10	10	100%
	Cutoff-150%	9	1*	10	90%
	Positive (>150%)	40	0	40	100%
Total		49	41	90	98.9%

COC		Cutoff: 20 ng/mL		Total	Agreement
		Positive	Negative		
HPLC/MS	Negative (<50%)	0	30	30	100%
	50%-cutoff	0	10	10	100%
	Cutoff-150%	8	2*	10	80%
	Positive (>150%)	40	0	40	100%
Total		48	42	90	97.8%

OPI		Cutoff: 40 ng/mL		Total	Agreement
		Positive	Negative		
HPLC/MS	Negative (<50%)	0	30	30	100%
	50%-cutoff	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
		Positive	Negative		
HPLC/MS	Negative (<50%)	0	30	30	100%
	50%-cutoff	0	10	10	100%
	Cutoff-150%	8	2*	10	80%
	Positive (>150%)	40	0	40	100%
Total		48	42	90	97.8%

* 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 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.

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
	3,4-Methylenedioxyamphetamine (MDA)	100 ng/mL
OPI	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
	Diacetylmorphine (Heroin)	100 ng/mL
THC	(-)-11-nor-Δ^9-THC-9-COOH	12 ng/mL
	11-Hydroxy-Δ^9-THC	300 ng/mL
	11-nor-Δ^8-THC-9-COOH	12 ng/mL
COC	Cocaine	20 ng/mL
	Benzoylecgonine hydrate	30 ng/mL
BZD	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
	Lormetazepam	20 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	Isoxsuprine	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	1µg/mL
Ampicillin	100 µg/mL	Meperidine	1µg/mL
Aspirin	100 µg/mL	Methadone	1,000 µg/mL
Benzoic acid	100 µg/mL	Methadol	100 µg/mL
Buprenorphine	100 µg/mL	Methanol	100 µg/mL
Butabarbital	100 µg/mL	Penicillin-G	100 µg/mL
Butabital	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	Gentisic acid	100 µg/mL
Hydroxybutyric acid	1,000 µg/mL	Ecgonine methyl ester	10 µg/mL
Imipramine	1µg/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		

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15°C 30°C	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	REF	Catalog number
	Manufacturer		Consult instructions for use
Σ n	Contains sufficient for <n> tests	2	Do not reuse

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