SmartCard™ 6 Oral Fluid Drug Test

AMP/COC/MET/OPI/BZO/THC
CAT# SCO-6MB

INTENDED USE

The SmartCard 6 Oral Fluid Drug Test is a rapid collection and test system for the qualitative detection of amphetamine (AMP), cocaine (COC), methamphetamine (MET), opiates (OPI), benzodiazepines (BZO), marijuana (THC) and their metabolites in human oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/ml)
AMP	d-Amphetamine	25
COC	Cocaine	20
MET	d-Methamphetamine	25
OPI	Morphine	10
BZO	Diazepam	5
THC	Δ^9-THC	100

The SmartCard 6 Oral Fluid Drug Test is used to obtain a visual, qualitative result and is intended ***for forensic use only***.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION OF TEST

Amphetamine/Methamphetamine, amphetamine, and metabolites are potent central nervous system stimulants. Acute higher doses induce euphoria, alertness, and sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Depending on the route of administration, amphetamine or methamphetamine can be detected in oral fluid as early as 5-10 minutes after use and can be detected in oral fluid for up to 72 hours after use[1].

Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine and its metabolites, benzoylecgonine, and ecgonine methylester, can be detected in oral fluid after use[2].

Opiates, such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. After opiates are used, morphine and its metabolites are present in oral fluid[2,3].

Benzodiazepines, are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Benzodiazepines can be detected in oral fluid after use[4].

Marijuana (THC) is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. THC (delta-9-tetrahydrocannabinol, tetrahydrocannabinol) is the major psychoactive compound found in marijuana. After marijuana use, cannabinoids, including THC, are found in oral fluid[3].

TEST PRINCIPLE

The SmartCard 6 Oral Fluid Drug Test is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites,which may be present in the oral fluid for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the oral fluid sample is allowed to migrate upward and dehydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the oral fluid, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein. When drug is present in the oral fluid, it will compete with drug-protein for the limited antibody sites. The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the oral fluid, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein on the test region. Therefore, the presence of the line on the test region indicates a **negative** result for the drug and the absence of the test line on the test region indicates a **positive** result for the drug. A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the oral fluid sample. The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

REAGENTS & MATERIALS SUPPLIED

- 25 individually wrapped test devices. Each device consists of two test strips in a plastic test strip holder. The test strip contains a colloidal gold pad coated with antibody and rabbit antibody. It also contains a membrane coated with drug-bovine protein conjugate in the test band and goat anti-rabbit antibody in the control band
- 25 individually wrapped collectors and screw caps
- One instruction sheet

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Gloves

WARNINGS AND PRECAUTIONS

- For forensic use only
- Test device should remain sealed until ready for use.
- Do not use the test kit after the expiration date.
- Proper handling and disposal of oral fluid specimen and used collector and device should be established.

STORAGE

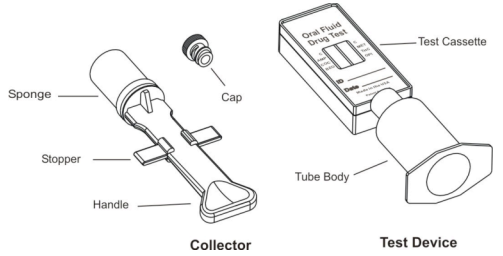
The SmartCard 6 Oral Fluid Drug Screen should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store test kits at temperature greater than 30°C.

SPECIMEN COLLECTION AND TESTING PROCEDURE

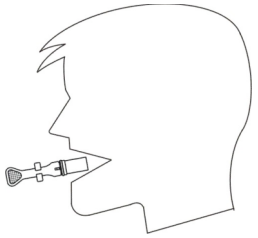
1. The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay.
2. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.
3. If test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
4. Do not open test device pouch until ready to perform the test.

Testing

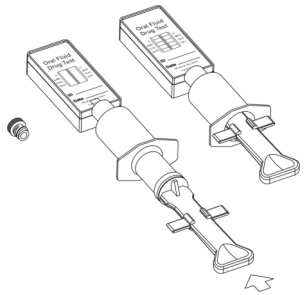
1. Remove the test device from the sealed pouch and place it on a clean and level surface.
2. Remove the collector and end cap from the sealed pouch and provide the collector to the donor.



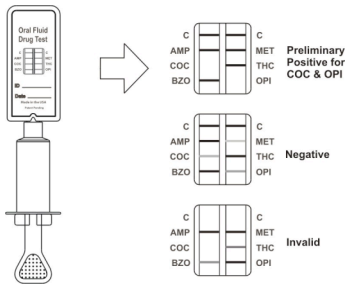
3. Instruct the donor to place the sponge end of the collector into the mouth actively swab the inside of the mouth and tongue to collect oral fluid fo a total of 3 minutes. Assure that the sponge becomes fully saturated Gentle pressing the sponge between the tongue and teeth will assis saturation.



4. Remove the collector from mouth and insert into the collection tube o the test device. Keep the test device at level position with the detectio window faced up. Gently push the collector to deliver the oral flui specimen into the collection tube until the red **Stop**per reaches the edg of the tube.

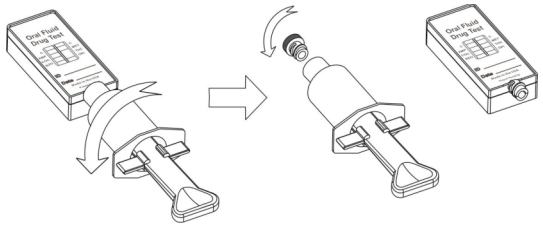


5. Lay the device on a flat surface and read results at 5 minutes. Do not interpret result after 1 hour.



6. If NEGATIVE results are observed, record the test result and dispose of all materials according to established procedures.

7. If POSITIVE results are observed, unscrew and remove the test device from collection tube. Screw the red cap onto the collection tube. Apply proper chain of custody procedures and forward the collected oral fluid specimen to a laboratory for confirmation.



INTERPRETATION OF RESULTS

Negative (-): Colored lines appear in both Control Region (C) and Test Region (Drug or T). The line in the control region is the control line, which is used to indicate proper performance of the device. The line in the test region is the drug probe line. The test line may have varying intensity either weaker or stronger in color than that of the control line. A negative result for a drug indicates that the concentration of that drug in urine is below the cutoff level.

Positive (+): Colored line appears in the control region (C). **No line appears in the test region (Drug or T)**. The complete absence of a test line indicates a positive result for that drug. A preliminary positive result for a drug indicates that the concentration of that drug in urine is at or above the cutoff level.

Invalid: No colored line appears in the control region. If the control line does not form, the test result is inconclusive and should be repeated.

QUALITY CONTROL

An internal procedural control is included in the test device. A line must form in the Control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that the proper sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid.

LIMITATIONS OF PROCEDURE

- The assay is designed for use with human oral fluid only.
- A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.
- There is a possibility that technical or procedural error as well other substances as factors not listed may interfere with the test and cause false results.

PERFORMANCE CHARACTERISTICS

Sensitivity

The sensitivity of the SmartCard 6 Oral Fluid Drug Test was evaluated by testing the devices with 20 negative saliva samples and 60 spiked oral fluid drug samples. The spiked drug samples consist of 20 specimens each spiked with the six drugs to 200%, 150%, and 50% of the cut-off levels. The results are summarized below.

Drug Test		0ng/ml	50%	150%	200%
AMP	(+)	0	0	20	20
	(-)	20	20	0	0
COC	(+)	0	1	20	20
	(-)	20	20	0	0
MET	(+)	0	0	19	20
	(-)	20	20	1	0
OPI	(+)	0	1	20	20
	(-)	20	20	0	0
BZO	(+)	0	0	20	20
	(-)	20	20	0	0
THC	(+)	0	1	18	20
	(-)	20	20	2	0

Specificity

The specificity for the SmartCard 6 Oral Fluid Drug Test was evaluated by testing various drugs, drug metabolites, and other compounds that are likely to be present in oral fluid. All compounds were prepared in artificial oral fluid solution. The following compounds produce positive results when tested at levels greater than the concentrations listed below.

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
Amphetamine			
d-Amphetamine	25	d-Methamphetamine	1250
dl-Amphetamine	75	(+/-)3,4-MDMA	1500
(+/-)3,4-MDA	100		
Cocaine			
Cocaine	20	Ecgonine	>100,000
Benzoylecgonine	20		
Methamphetamine			
d-Methamphetamine	25	d-Amphetamine	2,500
(+/-)3,4-MDMA	75	l-Methamphetamine	500
(+/-)3,4-MDA	>10,000		
Opiates			
Morphine	10	Hydrocodone	20
Codeine	10	Hydromorphone	20
Ethylmorphine	10	Nalorphine	500
Heroin	30		
Benzodiazepines			
Oxazepam	5	Flunitrazepam	5
Alprazolam	7.5	Flurazepam	5
Bromazepam	4	Lorazepam	10
Chlordiazepoxide	5	Medazepam	5
Clobazam	20	Nitrazepam	5
Clonazepam	10	Nordiazepam	3
Clorazepate	3	Prazepam	10
Desalkylflurazepam	4	Temazepam	4
Diazepam	7.5	Triazolam	7.5
Estazolam	5		

THC

Δ9-THC	100	Cannabinol	2,000
Δ8-THC	150	Cannabidiol	>10,000
11-nor-Δ9-THC-9-COOH	15		

Interference

The following compounds were spiked into an oral fluid solution and teste with the SmartCard 6 Oral Fluid Drug Screen. No false positive was found fo the following compounds when tested at concentrations up to 10 μg/ml.

Acetaminophen	Ibuprofen
Acetone	(+/-)-Isoproterenol
Albumin	Ketamine
Ampicillin	Levorphanol
Ascorbic Acid	Lidocaine
Aspartame	(+)-Naproxen
Aspirin	Niacinamide
Atropine	Nicotine
Benzocaine	(+/-)-Norephedrine
Bilirubin	Oxalic Acid
Caffeine	Penicillin-G
Chloroquine	Pheniramine
(+)-Chlorpheniramine	Phenothiazine
(+/-)-Chlorpheniramine	l-Phenylephrine
Creatine	β-Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethorphan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride
Erythromycin	Sulindac
Ethanol	Theophylline
Furosemide	Tyramine
Glucose	4-Dimethylaminoantipyrine
Guaiacol Glyceryl Ether	(1R,2S)-(-)-N-Methyl-Ephedrine
Hemoglobin	

REFERENCES

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4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," *J Anal Tox*. 1984 Sep-Oct.; 8 (5), pp 197-201.