

SalivaScreen**SALIVASCREEN VI
008S600****ulti
med****A rapid, screening test for the simultaneous, qualitative detection of multiple drugs and metabolites in human oral fluid.****For professional in vitro diagnostic use only.****INTENDED USE**

The **SalivaScreen VI** is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamines, Cocaine, Marijuana, Methamphetamines, Opiates, and Phencyclidine and their metabolites in oral fluid at the following cut-off concentrations.

TEST	SYMBOL	CALIBRATOR	CUT-OFF (ng/mL)	DETECTION TIME
Amphetamine	AMP	D-Amphetamine	50	10 min – 72 hrs
Cocaine	COC	Benzoylcegonine	20	10 min – 24 hrs
Marijuana	THC	11-nor- Δ^9 -THC-9 COOH	12	up to 14 hrs
Methamphetamine	MET	D-Methamphetamine	50	10 min – 72 hrs
Opiates	OPI	Morphine	40	1 hr – several days*
Phencyclidine	PCP	Phencyclidine	10	-

SUMMARY

The **SalivaScreen VI** will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

AMP: Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion.

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (*erythroxylum coca*).

THC: Tetrahydrocannabinol, the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.

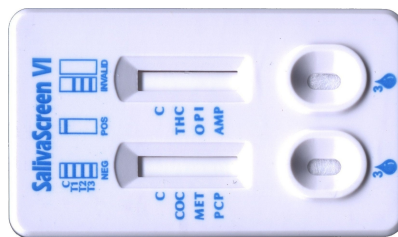
MET: Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion.

OPI: The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates control pain by depressing the CNS, and demonstrate addictive properties when used for sustained periods of time. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation.

*The window of detection varies for different opiates. Codeine can be detected within one hour and up to 7-21 hours after a single oral dose. Opiates is detectable for several days after a dose.

PCP: Phencyclidine is a hallucinogen and, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity.

The **SalivaScreen VI** provides only a preliminary analytical 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 judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PRINCIPLE

The **SalivaScreen VI** is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural

control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The **SalivaScreen VI** contains drug protein conjugates and mouse monoclonal antibody-coupled particles specific to each drug coated on the membrane. A goat anti-mouse antibody is employed in each control line.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not moisten nitrocellulose membrane with samples.
- Use proper sample volume (min 180 μ l per assay).
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent
- The used test device should be discarded according to federal state and local regulations.

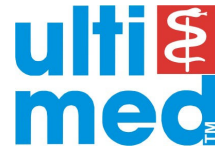
STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use.

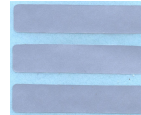
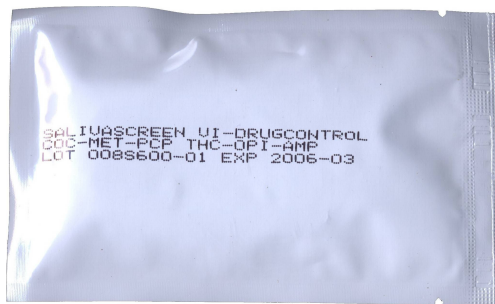
- Do not freeze.
- Do not use beyond the expiration date.



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MATERIALS PROVIDED



- SalivaScreen VI,**
- single pouched
 - Collection tubes
 - Collector, single pouched
 - Tamper evident tape

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this test. Oral fluid collected at any time of the day may be used. Specimen is stable up to two days refrigerated (2-8°C). Specimen is also stable frozen (-20°C) for up to three days. For ideal shipment conditions, transport specimen using ice packs (2-8°C).

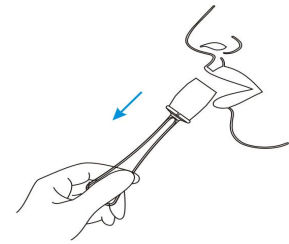
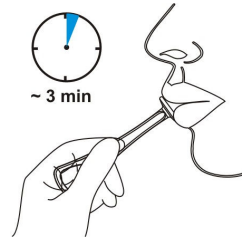
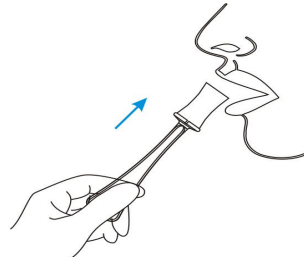
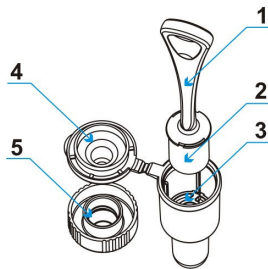
- 1: Collector
- 2: Sponge
- 3: Filter Board

- 4: Cap
- 5: Cap Cover

Insert the sponge end of the collector into the mouth:

Swab sponge continuously between cheek and teeth until the sponge becomes fully saturated.

Remove collector from mouth



DIRECTIONS FOR USE

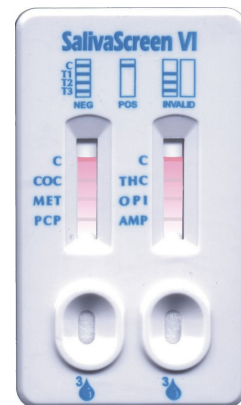
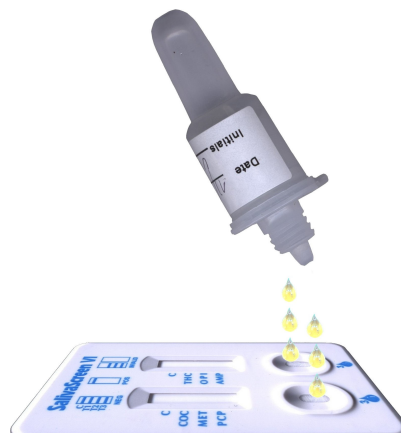
Note: Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Remove the **SalivaScreen VI** from the sealed pouch and use it as soon as possible.

Push collector into the collection chamber and press it down to release as much liquid as possible. Discard the collector.

Place the cap on the collection tube.

Place the test device on a clean and level surface. Unscrew cap cover from the collection tube. Invert the collection tube and transfer 3 drops of oral fluid (approximately 180 µL) into specimen well of the test device, and start the timer. Avoid trapping air bubbles in the specimen well. Replace cap cover on the collection tube.

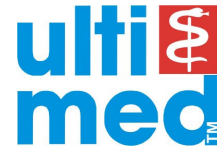
Wait for the colored line(s) to appear. Read results at 10 minutes. Do not read results after more than 1 hour.



max 10 min



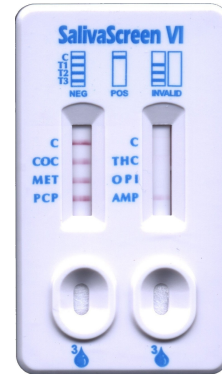
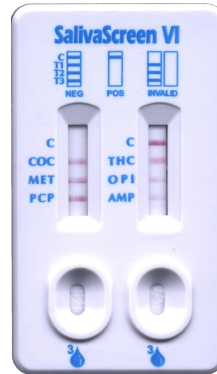
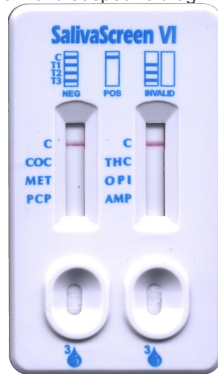
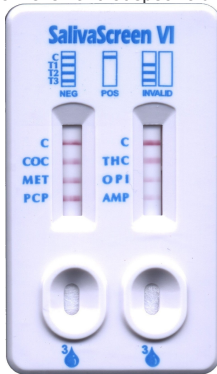
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Secure collection tube with tamper evident tape and send to the laboratory for confirmation if necessary.

INTERPRETATION OF RESULTS

NEGATIVE*	POSITIVE	INVALID
A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.	A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.	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 device. If the problem persists, discontinue using the lot immediately and contact your local distributor.



*NOTE: The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line. Examples:

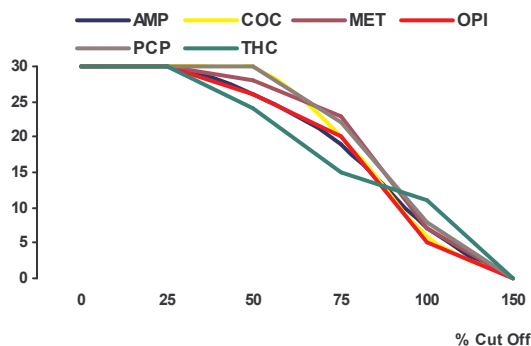
QUALITY CONTROL

A procedural control is included in **SalivaScreen VI**. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, 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.

LIMITATIONS

- 1 The **SalivaScreen VI** provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is preferred confirmatory methods.
- 2 A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- 3 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.

PERFORMANCE CHARACTERISTICS



Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of $\pm 50\%$ cut-off and $\pm 25\%$ cut-off and tested with the **SalivaScreenVI**. The results are shown on the left:

The presence of T-line is shown at different drug of abuse concentrations. To screen saliva for drugs of abuse highly sensitive tests are most preferable.

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the **SalivaScreen VI** identified positive results at 10 minutes.

AMPHETAMINES	[ng / mL]	OPIATES	[ng / mL]
D-Amphetamine	50	Codeine	10
DL-Amphetamine	125	Ethylmorphine	25
(+)-3,4-Methylenedioxyamphetamine (MDA)	150	6-Monoacetylmorphine	25
p-Hydroxyamphetamine	800	Morphine	40
Tryptamine	1,500	Diacetylmorphine	50
β-Phenylethylamine	4,000	Morphine 3-β-D-Glucuronide	50
COCAINE & METABOLITES		Hydrocodone	100
Benzoylcegonine	20	Hydromorphone	100
Cocaine HCl	20	Levorphanol	400
Cocaethylene	25	Norcodeine	1,500
Ecgonine HCl	1,500	Thebaine	1,500
Ecgonine methylester	12,500	Oxycodone	6,000
MARIJUANA & METABOLITES		Nalorphine	10,000
11-nor-Δ ⁸ -THC-9 COOH	2	Normorphine	12,500
11-nor-Δ ⁹ -THC-9 COOH	12	Oxymorphone	25,000
Δ ⁸ -THC	6,000	PHENCYCLIDINE	
Δ ⁹ -THC	10,000	Phencyclidine	10
Cannabinol	12,500	Tetrahydrozoline	50,000
METHAMPHETAMINES			
D-Methamphetamine	50		
3,4-Methylenedioxymethamphetamine (MDMA)	50		
p-Hydroxymethamphetamine	400		
(1R,2S) - (-) Ephedrine	400		
Procaine	2,000		
L-Phenylephrine	4,000		
Methoxyphenamine	25,000		
Fenfluramine	60,000		

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the **SalivaScreenVI** when tested at concentrations up to 10 µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Dextromethorphan	Meperidine	D-Pseudoephedrine
Acetophenetidin	Diclofenac	Meprobamate	Quinacrine
N-Acetylprocainamide	Diflunisal	Methoxyphenamine	Quinine
Acetylsalicylic acid	Digoxin	Methylphenidate	Quindine
Aminopyrine	Diphenhydramine	Nalidixic acid	Ranitidine
Amoxicillin	Ecgonine methyl ester	Naloxone	Salicylic acid
Ampicillin	L -Ψ-Ephedrine	Naltrexone	Serotonin
L-Ascorbic acid	β-Estradiol	Naproxen	Sulfamethazine
Apomorphine	Estrone-3-sulfate	Niacinamide	Sulindac
Aspartame	Ethyl-p-aminobenzoate	Nifedipine	Tetracycline
Atropine	L(-)-Epinephrine	Norethindrone	Tetrahydrocortisone 3-acetate
Benzilic acid	Erythromycin	D-Norpropoxyphene	Tetrahydrocortisone 3 (β-D-glucuronide)
Benzoic acid	Fenopropfen	Noscapine	Tetrahydrozoline
Benzphetamine	Furosemide	D/L-Octopamine	Thiamine
Bilirubin	Gentisic acid	Oxalic acid	Thioridazine
D/L-Brompheniramine	Hemoglobin	Oxolinic acid	D/L-Tyrosine
Caffeine	Hydralazine	Oxymetazoline	Tolbutamide
Cannabidiol	Hydrochlorothiazide	Papaverine	Triamterene
Chloralhydrate	Hydrocortisone	Penicillin-G	Trifluoperazine
Chloramphenicol	o-Hydroxyhippuric acid	Pentazocine hydrochloride	Trimethoprim
Chlorothiazide	p-Hydroxyamphetamine	Perphenazine	Tryptamine
D/L-Chloropheniramine	p-Hydroxytyramine	Phenelzine	D/L-Tryptophan
Chlorpromazine	Ibuprofen	Trans-2-phenylcyclo-propylamine hydrochloride	Tyramine
Chloroquine	Iproniazid	L-Phenylephrine	Uric acid
Cholesterol	D/L-Isoproterenol	β-Phenylethylamine	Verapamil
Clonidine	Isoxsuprine	Phenylpropanolamine	Zomepirac
Cortisone	Ketamine	Prednisolone	
L-Cotinine	Ketoprofen	Prednisone	
Creatinine	Labetalol	D/L-Propranolol	
Deoxycorticosterone	Loperamide	D-Propoxyphene	

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