SalivaScreen

SALIVASCREEN VI
008S601

ultimed TM

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 Methadone and their metabolites in oral fluid at the following cut-off concentrations.

TEST	SYMBOL	CALIBRATOR	CUT-OFF (ng/mL)	DETECTION TIME
Cocaine	**COC**	Benzoylecgonine	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
Methadone	**MTD**	Methadone	30	up to 2 days
Opiates	**OPI**	Morphine	40	1 hr – several days*
Amphetamine	**AMP**	D-Amphetamine	50	10 min – 72 hrs

SUMMARY

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

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anaesthetic 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.

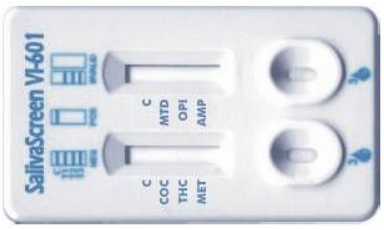
MTD: Methadone is an analgesic compound most frequently used for the treatment of opiate addiction. Using known half life data for plasma, the detection window in saliva is expected to be up to 2 days after use.

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 are detectable for several days after a dose.

AMP: Amphetamine is a sympathomimetic amine which is not used anymore for therapeutic use due to its addictive potential. The drug is often self-administered by nasal inhalation or oral ingestion.

The **SalivaScreen VI** provides only a preliminary analytical test 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 coloured 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 coloured line will not form in the test line region.
A drug-positive oral fluid specimen will not generate a coloured 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 coloured 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 µl 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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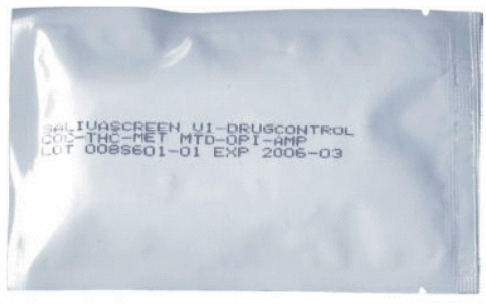
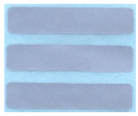
MATERIALS PROVIDED





SalivaScreen VI,
- single pouched
- Collection chamber
- Collector, single pouched
- Security tap

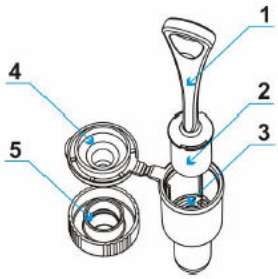
MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

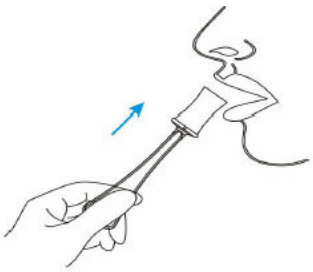
SPECIMEN COLLECTION AND PREPARATION

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).

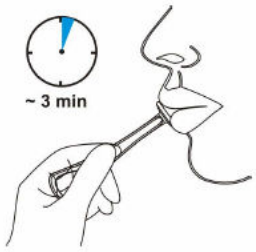
1: Collector
2: Sponge
3: Filter Board
4: Cap
5: Cap Cover



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

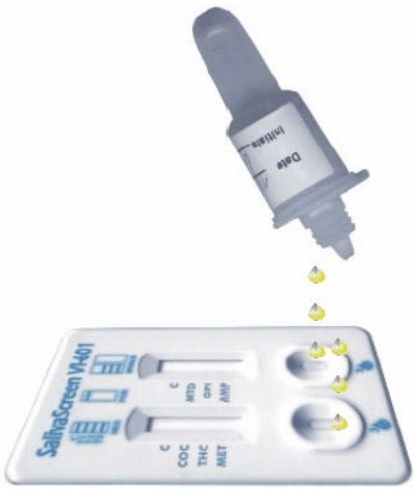
Note: Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Remove the **SalivaScreen VI** from the sealed pouch and use it as soon as possible.

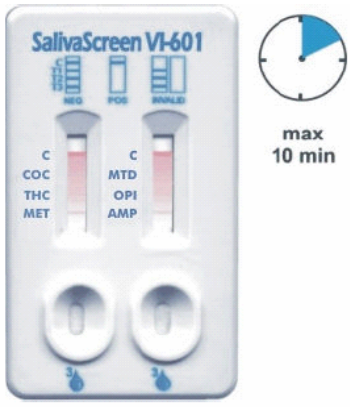
Push collector into the collection chamber and press it down to release as much liquid as possible. Discard the collector.

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





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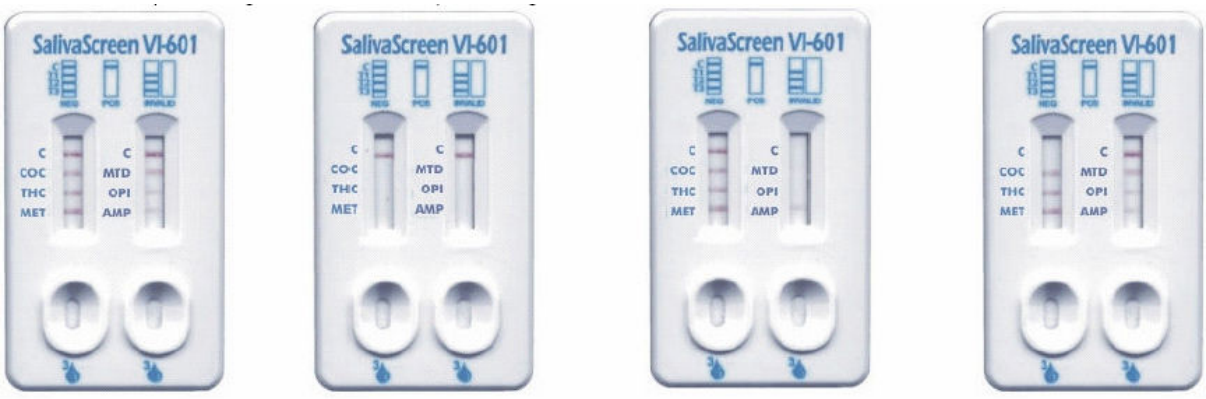
Secure collection tube with tamper evident tape and send to the laboratory for confirmation if necessary.

INTERPRETATION OF RESULTS

NEGATIVE*	POSITIVE	INVALID
A coloured line in the control line region (C) and a coloured 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 coloured 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 colour in the test line region (T) may vary, but it should be considered negative whenever there is even a faint coloured line.

Examples:

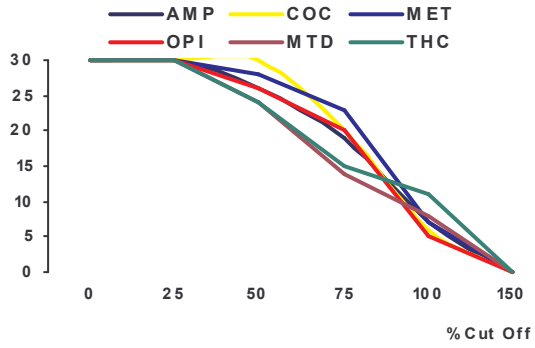
QUALITY CONTROL

A procedural control is included in **SalivaScreen VI**. A coloured 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 ± 50% cut-off and ± 25% cut-off and tested with the **SalivaScreen VI**. 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.

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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]
D-Amphetamine	50
DL-Amphetamine	125
(+)3,4-Methylenedioxyamphetamine (MDA)	150
p-Hydroxyamphetamine	800
Tryptamine	1,500
ß-Phenylethylamine	4,000
COCAINE & METABOLITES	
Benzoylecgonine	20
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine methylester	12,500
MARIJUANA & METABOLITES	
11-nor-Δ^8-THC-9 COOH	2
11-nor-Δ^9–THC-9 COOH	12
Δ^8–THC	6,000
Δ^9–THC	10,000
Cannabinol	12,500
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

OPIATES	[ng / mL]
Codeine	10
Ethylmorphine	25
6-Monoacetylmorphine	25
Morphine	40
Diacetylmorphine	50
Morphine 3-β-D-Glucuronide	50
Hydrocodone	100
Hydromorphone	100
Levorphanol	400
Norcodeine	1,500
Thebaine	1,500
Oxycodone	6,000
Nalorphine	10,000
Normorphine	12,500
Oxymorphone	25,000
METHADONE	
Methadone	30
Doxylamine	50,000
Estrone-3-Sulfate	50,000
Phencyclidine	50,000

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 **SalivaScreen VI** when tested at concentrations up to 10 μg/mL.

Non Cross-Reacting Compounds

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

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