SCREEN®

SCREEN MIDSTREAM 6-S-MED (Oral Fluid) Package Insert

REF: SC-0333-25	English

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human saliva. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

INTENDED USE

The Multi-Drug Rapid Test Midstream for AMP/COC/OPI/THC/MET/MDMA is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in saliva at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	40
Methamphetamine (MET)	d-Methamphetamine	40
Marijuana (THC)	11-nor-Δ^9 -THC-9 COOH	10
Cocaine (COC)	Benzoylecgonine	30
Opiates (OPI/MOP)	Morphine	40
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50

This assay 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) is the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The Multi-Drug Rapid Test Midstream for AMP /MET /COC /OPI /THC /MDMA and their metabolites is a rapid, saliva screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human saliva.

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes following use[1]. Amphetamine can be detected in oral fluids for up to 72 hours after use[1].

The amphetamine assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the amphetamine concentration in oral fluid exceeds 40ng/ml.

Methamphetamine (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. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use[1]. Methamphetamine can be detected in oral fluids for up to 72 hours after use[1].

The Methamphetamine assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the methamphetamine concentration in oral fluid exceeds 40ng/ml.

Cocaine (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].

The cocaine assay contained within the Multi-Drug Rapid Test Midstream for cocaine and opiates yields a positive result when the cocaine metabolite in oral fluid exceeds 30ng/ml.

Opiates (OPI/MOP)

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 act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. 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. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose[2]. Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin.

The opiates assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the opiates concentration in oral fluid exceeds 40 ng/ml.

Marijuana (THC)

11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH), the metabolite of THC (Δ^9-tetrahydrocannabinol), is detectable in saliva 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[3]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[3].

The THC assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the Δ^9-tetrahydrocannabinol concentration in oral fluid exceeds 10ng/ml.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The MDMA assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the MDMA concentration in saliva exceeds 50ng/ml.

PRINCIPLE

The Multi-Drug Rapid Test Midstream for AMP/MET/COC/OPI/THC/MDMA 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 test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Cocaine, Opiates, ∆9-THC-COOH, Methadone, Methylenedioxymethamphetamine and Synthetic Marijuana.

PRECAUTIONS

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and Midstream should be discarded according to federal, state and local regulations.

STORAGE AND STABILTY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test Midstream must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

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 Midstream should be used with this assay. Oral fluid collected at any time of the day may be used.

MATERIALS

Materials Provided

·Test Midstreams ·Package insert

Materials Required but Not Provided

·Timer

DIRECTIONS FOR USE

Allow the test Midstream, specimen, and/or controls to reach room temperature(15-30°C) prior to testing. 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.

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
2. Take off the Device cap and collect oral fluid specimen as follows.

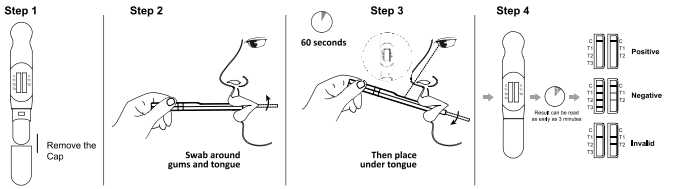
Important: Place the tongue against the upper and lower jaws and roots to enrich the oral fluid. Insert the sponge end into the mouth, actively swab around the gums on both sides of the mouth (10-15 times) to assist saturation.

Put the absorbent wick under the tongue to collect oral fluid until the flow appear in the test windows (approximately 60 seconds) and then take out the device and start a timer.

If no flow appeared repeat the procedure in steps above until the flow appear. If no flow appeared after triplicate of steps above, discard the device, review procedures with the donor and repeat the test using a new device.

3. Place the test device on a clean and level surface.
4. **Read the test result at 3-10 minutes.**

If all lines are clearly visible at 3 minutes or sooner, then the test can be interpreted as negative and discarded. If any lines are not visible at 3 minutes, then the test should be re-read at 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* Two colored lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

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

POSITIVE: One colored line appears in the control region (C). No line appears in the test region (Drug/T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: 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 panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

QUALITY CONTROL

A procedural control is included in the test. 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.

LIMITATIONS

1. The Multi-Drug Rapid Test Midstream 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 cutoff level of the assay.

PERFORMANCES CHARACTERISTICS

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off, ± 25% cut-off and +300% cut-off and tested with the Multi-Drug Rapid Test Midstream. The results are summarized below.

Drug conc. (Cut-off range)	n	AMP		THC		COC		OPI		MET		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	27	3	27	3	27	3	28	2	26	4
Cut-off	30	15	15	12	18	15	15	13	17	16	14	19	11
+25% Cut-off	30	7	23	8	22	8	22	7	23	6	24	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Multi-Drug Rapid Test Midstream for AMP/MET/COC/OPI/THC/MDMA identified positive results at a read time of 10 minutes.

Compound	**ng/mL**
AMPHETAMINE (AMP)	
d-Amphetamine	40
d/l-Amphetamine	100
ß-Phenylethylamine	25,000
Tryptamine	12,500
p-Hydroxyamphetamine	100
(+)3,4-Methylenedioxyamphetamine (MDA)	100
l-Amphetamine	25,000
Methoxyphenamine	12,500
METHAMPHETAMINE (MET)	
d-Methamphetamine	40
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
Mephentermine	1,500
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine (R)-(-)-Phenylephrine	6,250
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
Ephedrine	400
Benzphetamine	25,000
MARIJUANA (THC)	
11-nor-Δ^9 -THC-9 COOH	10
Cannabinol	10
Δ^8 -THC	6,000
Δ^9 -THC	10,000
11-nor-Δ^8-THC-9 COOH	2
COCAINE (COC)	
Benzoylecgonine	30
Cocaine	30
Cocaethylene	30
Ecgonine	1,500
Ecgonine methyl ester	12,500
OPIATES (OPI)	
Morphine	40
Codeine	40
Ethylmorphine	25
Hydromorphine	100
Dihydrocodeine	40
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-D-Glucuronide	50
Norcodeine	6,250
Normorphine	25,000
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	2,000
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine	4
Methylenedioxymethamphetamine (MDMA)	
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)	50
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)	50
3,4-Methylenedioxyethyl-amphetamine (MDE)	50
MDEA	50
MBDB	50
l-Methamphetamine	25,000

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 Multi-Drug Rapid Test Midstream when tested with at concentrations up to 100 µg/mL.

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

BIBLIOGRAPHY

1. Moolchan, E., et al, “Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine”, Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
2. Kim, I, et al, “Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration”, Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, “Drugs of Abuse in Saliva: A Review,” J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9

INDEX OF SYMBOLS

	Consult Instructions For Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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