

SCREEN[®]

SCREEN MIDSTREAM (Oral Fluid) Package Insert

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/MET/COC/OPI/MOP/THC/PCP/MTD/BZO/OXY/COT/SMA/K2 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	50
Methamphetamine (MET)	d-Methamphetamine	50
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	12
Phencyclidine (PCP)	Phencyclidine	10
Cocaine (COC)	Benzoyllecgonine	20
Opiates (OPI/MOP)	Morphine	40
Methadone (MTD)	Methadone	30
Oxycodone (OXY)	Oxycodone	20
Cotinine (COT)	Cotinine	20
Benzodiazepines (BZO)	Oxazepam	20
Synthetic Marijuana (SMA/K2)	JWH -018, JWH- 073	25

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/PCP/MTD/BZO/OXY/COT/SMA/K2 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 use¹. Amphetamine can be detected in oral fluids for up to 72 hours after use¹.

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 use¹. Methamphetamine can be detected in oral fluids for up to 72 hours after use¹.

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 use¹. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use¹.

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 40ng/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 dose². Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin.

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 cavity³. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use³.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin[®], Tylox[®], Percodan[®] and Percocet[®]. While Tylox[®], Percodan[®] and Percocet[®] contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

Phencyclidine (PCP)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in an Emergency Department, PCP was detected in the oral fluid of 79 patients at levels as low as 2ng/ml and as high as 600ng/ml⁴.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists⁵.

Cotinine (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

Although nicotine is excreted in oral fluid, the relatively short half-life of the drug makes it an unreliable maker for tobacco use. Cotinine, however, demonstrates a substantially longer half-life than nicotine bears a high correlation with plasma cotinine levels and has been found to be the best maker for smoking status compared with oral fluid nicotine measurement, breath carbon monoxide testing and plasma thiocyanate testing. The window of detection for cotinine in oral fluid test is expected to be up to 1-2 days after nicotine use.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception⁶.

Synthetic Marijuana (SMA/K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness⁵. Elevated levels of oral fluid metabolites are found within hours of exposure and remain

detectable window up to 24-48 hours after smoking (depending on usage/dosage).

PRINCIPLE

The Multi-Drug Rapid Test Midstream for AMP/MET/COC/OPI/MOP/THC/PCP/MTD/BZO/OXY/COT/SMA/K2 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, Morphine, Marijuana, Phencyclidine, Methadone, Oxycodone, Cotinine, Benzodiazepines 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 STABILITY

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

- Test Midstreams
 - Package insert
 - Timer
- Materials Required but Not Provided**

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

0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	27	3	27	3	25	5	26	4
Cut-off	30	16	14	12	18	20	10	13	17	15	15
+25% Cut-off	30	6	24	8	22	4	26	4	26	3	27
+50% Cut-off	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

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/PCP/MTD/BZO/OXY/COT/SMA/K2 identified positive results at a read time of 10 minutes.

Compound	ng/ml
AMPHETAMINE (AMP50)	
d-Amphetamine	50
d/l-Amphetamine	100
β-Phenylethylamine	25,000
Tryptamine	12,500
p-Hydroxyamphetamine	100
(+)-3,4-Methylenedioxyamphetamine (MDA)	100
l-Amphetamine	25,000
Methoxyphenamine	12,500
METHAMPHETAMINE (MET50)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
Mephentermine	1,500
3,4-Methylenedioxyamphetamine (MDMA)	50
l-Phenylephrine (R)-(-)-Phenylephrine	6,250
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
Ephedrine	400
Benzphetamine	25,000
MARIJUANA (THC12)	
11-nor-Δ ⁹ -THC-9 COOH	12
Cannabinol	12,500
Δ ⁸ -THC	6,000
Δ ⁹ -THC	10,000
11-nor-Δ ⁸ -THC-9 COOH	12
COCAINE (COC20)	
Benzoyllecgonine	20
Cocaine	20
Cocaethylene	30
Ecgonine	1,500
Ecgonine methyl ester	12,500
OPIATES (OPI/MOP40)	
Morphine	40
Codeine	25
Ethylmorphine	25
Hydromorphone	100
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	25
OXYCODONE (OXY20)	
Oxycodone	20
Oxymorphone	40
Levorphanol	10,000
Hydrocodone	1,500
Hydromorphone	10,000
Naloxone	5,000

Naltrexone	5,000
Cotinine (COT20)	
(-)-Cotinine	20
(-)-Nicotine	300
Marijuana Sintetica (SMA/K2-25)	
JWH-018 5-Pentanoic acid metabolite	25
JWH-018 5-Hydroxypentyl metabolite	250
JWH-073 4-butanoic acid metabolite	25
JWH-073 4-Hydroxybutyl metabolite	250
JWH-018 4-Hydroxypentyl metabolite	200
Fenciclidina (PCP10)	
Phencyclidine	10
4-Hydroxyphencyclidine	2,500
Metadone (MTD30)	
Methadone	30
LAAM	200
Disopyramide	400
Doxylamine	12,500
(+)-Chlorpheniramine	6,250
Nor-LAAM	12,500
Benzodiazepine (BZO20)	
Alprazolam	10
a-hydroxyalprazolam	100
Bromazepam	50
Chlordiazepoxide	50
Clobazam	10
Clonazepam	25
Clorazepatedipotass	25
Delorazepam	50
Desalkylflurazepam	10
Diazepam	100
Estazolam	400
Flunitrazepam	10
(±) Lorazepam	200
RS-Lorazepamglucuronide	10
Midazolam	400
Nitrazepam	10
Norchlordiazepoxide	10
Nordiazepam	50
Oxazepam	20
Temazepam	10
Triazolam	200

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-Chlorpheniramine	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
Diffunisal	Iproniazid	Oxalic acid
Diphenhydramine	Isosuprine	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	Phenylpropranolamine	d/l-Tyrosine
Aspartame	Prednisone	Triamterene
Benzilic acid	d-Propoxyphene	Trimethoprim
Benzphetamine	Quinacrine	Tyramine
Caffeine	Quindine	Verapamil
Chloramphenicol	Salicylic acid	Zomepirac

BIBLIOGRAPHY

- 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.
- Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
- Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9.
- McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201.
- Lane JC, Tennison MB, Lawless ST, et al. Movement disorder after withdrawal of fentanyl infusion. J Pediatr, 1991, 119 (4) : 649-651.
- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488

INDEX OF SYMBOLS

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

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