



Multi-Drug Rapid Test Midstream (Oral Fluid) Package Insert

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/THC/PCP/MTD/BZO/OXY/COT/SMA 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)	Benzoylcegonine	20
Opiates (OPI)	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) and gas chromatography/tandem mass spectrometry (GC/MS/MS) are 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 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.

The amphetamine assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the amphetamine concentration in oral fluid exceeds 50 ng/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 use¹. Methamphetamine can be detected in oral fluids for up to 72 hours after use¹.

The Methamphetamine assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the methamphetamine concentration in oral fluid exceeds 50 ng/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 benzoylcegonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use¹. Cocaine and benzoylcegonine can be detected in oral fluids for up to 24 hours after use¹.

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 20 ng/mL.

Opiates (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 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 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.

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

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 4 ng/mL.

Phencyclidine (PCP)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL⁴.

The PCP assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the PCP concentration in oral fluids exceeds 10 ng/mL.

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 therapists.

The MTD assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the MTD concentration in saliva exceeds 30 ng/mL.

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 opiate 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.

The OXY assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the OXY concentration in saliva exceeds 20 ng/mL.

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 saliva, 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 saliva nicotine measurement, breath carbon monoxide testing and plasma thiocyanate testing. The window of detection for cotinine in saliva at a cutoff level of 20 ng/mL 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 perception.

The BZO assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the BZO concentration in saliva exceeds 20ng/mL.

Synthetic Marijuana (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 illness.

Elevated levels of oral fluid/saliva metabolites are found within hours of exposure and remain detectable window up to 24-48 hours after smoking (depending on usage/dosage).

The K2 assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the K2 concentration in saliva exceeds 20ng/mL.

ASSAY PRINCIPLE

The Multi-Drug Rapid Test Midstream for AMP/MET/COC/OPI/THC/PCP/MTD/BZO/OXY/COT/SMA 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, Δ^9 -THC-COOH, 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.

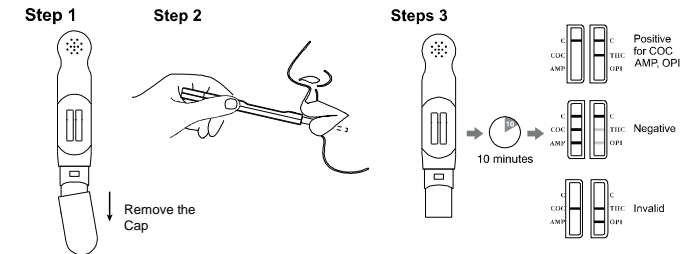
MATERIALS

- Test Midstream
- Materials Provided
 - 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.

- Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
- Remove the midstream from the sealed pouch and insert the tongue under to collect oral fluid until the control line appear.
- Place the test Midstream on a clean and level surface. See illustration below.
- A negative result is visible at 5 minutes. Read final results at 10 minutes.** Do not read results after 1 hour.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

***NOTE:** The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your 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

- 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) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is preferred confirmatory methods.
- 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.

【PERFORMANCE 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		MET		THC	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	29	1
-25% Cut-off	30	27	3	28	2	/	/
Cut-off	30	15	15	16	14	14	16
+25% Cut-off	30	7	23	6	24	/	/
+50% Cut-off	30	0	30	0	30	2	28
+300% Cut-off	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	PCP		COC		OPI		K2	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	27	3	26	4
Cut-off	30	14	16	15	15	13	17	15	15
+25% Cut-off	30	10	20	8	22	7	23	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	MTD		OXY		COT		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	25	5	26	4
Cut-off	30	15	15	20	10	20	10	14	16
+25% Cut-off	30	7	23	4	26	7	23	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	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/OXY/COT/BZO/SMA identified positive results at a read time of 10 minutes.

Compound	ng/mL
AMPHETAMINE (AMP)	
d-Amphetamine	50
d/l-Amphetamine	100
β-Phenylethylamine	25,000
Tryptamine	12,500
p-Hydroxyamphetamine	100
(+)-3,4-Methylenedioxymphetamine (MDA)	100
l-Amphetamine	25,000
Methoxyphenamine	12,500
METHAMPHETAMINE (MET)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
Mephentermine	1,500
3,4-Methylenedioxymphetamine (MDMA)	50
l-Phenylephrine (R)-(-)-Phenylephrine	6,250
Procaine	2,000

1(R,2S) - (-) Ephedrine	400
Ephedrine	400
Benzphetamine	25,000
MARIJUANA (THC)	
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	2
COCAINE (COC)	
Benzoylcegonine	20
Cocaine	20
Cocaehtylene	30
Ecgonine	1,500
Ecgonine methyl ester	12,500
OPIATES (OPI)	
Morphine	40
Codeine	25
Ethylmorphine	25
Hydromorphine	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
PHENCYCLIDINE (PCP)	
Phencyclidine	10
4-Hydroxyphencyclidine	2,500
OXYCODONE (OXY)	
Oxycodone	20
Oxymorphone	40
Levorphanol	10,000
Hydrocodone	1,500
Hydromorphone	10,000
Naloxone	5,000
Naltrexone	5,000
COTININE (COT)	
(-)-Cotinine	20
(-)-Nicotine	300
Synthetic Marijuana (K2)	
JWH-018 5-Pentanoic acid metabolite	25
JWH-073 4-butanoic acid metabolite	25
JWH-018 4-Hydroxypentyl metabolite	200
JWH-018 5-Hydroxypentyl metabolite	250
JWH-073 4-Hydroxybutyl metabolite	250
Benzodiazepines (BZO)	
Alprazolam	10
α-hydroxyalprazolam	100
Bromazepam	50
Chlordiazepoxide	50
Clobazam	10
Clonazepam	25
Clorazepatedipotass	25
Delorazepam	50
Desalkylflurazepam	10
Diazepam	100
Estazolam	420
Flunitrazepam	10
(±) Lorazepam	200
RS-Lorazepamglucuronide	10
Midazolam	420
Nitrazepam	10
Norchlordiazepoxide	10
Nordiazepam	50
Oxazepam	20
Temazepam	10
Triazolam	200

ETHADONE (MTD)	
Methadone	30
Disopyramide	400
(+)-Chlorpheniramine	6,250
LAAM	200
Doxylamine	12,500
Nor-LAAM	12,500

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

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- Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", *Clin Chem*, 2002 Sept.; 48 (9), pp 1486-96.
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Attention, see instructions for use		Index of Symbols		Authorized Representative	
	Attention, see 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				



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