

## Multi-Drug Rapid Test B 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 /MDMA /OXY /COT /K2 /BZO/KET/BAR is a lateral flow chromatographic immunosasay for the qualitative detection of multiple drugs and drug metabolites in saliva at the following cut-off

Test	Calibrator	Cut-off (ng/mL)
Benzodiazepines (BZO)	Oxazepam	30
Amphetamine (AMP)	d-Amphetamine	50
Methamphetamine (MET)	d-Methamphetamine	50
Marijuana (THC)	11-nor-∆9 -THC-9 COOH	50
Phencyclidine (PCP)	Phencyclidine	10
Cocaine (COC)	Benzoylecgonine	20
Opiates (OPI/MOP)	Morphine	40
Methadone (MTD)	Methadone	30
Oxycodone (OXY)	Oxycodone	20
Cotinine(COT)	Cotinine	20
Methylenedioxymethamphetamine(MD	DMA)d,l-Methylenedioxymethamphet	amine50
Synthetic Marijuana(K2)	JWH -018, JWH- 073	25
Ketamine(KET)	Ketamine	50
Barbiturates(BAR)	Secobarbital	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) 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 /MDMA /OXY /COT /K2 /BZO/KET/BAR 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<sup>1</sup>. Amphetamine can be detected in oral fluids for up to 72 hours after use<sup>1</sup>

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

The Methamphetamine assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the methamphetamine concentration in oral fluid exceeds 50ng/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<sup>1</sup>. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use

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 20ng/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 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- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid ( $\Delta^9$ -THC-COOH), the metabolite of THC  $(\Delta^9$ -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 Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use

The THC assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the  $\Delta^9$ -tetrahydrocannabinol concentration in oral fluid exceeds 50ng/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 10ng/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 30ng/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 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.

The OXY assay contained within the Multi-Drug Rapid Test Midstream yields a positive result when the OXY concentration in saliva exceeds 20ng/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 the autonomic ganglia and central nervous system when in numeric naturals recording to a dispersion 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

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

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

Synthetic Marijuana (K2)

Sýnthetic 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

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 30ng/ml...

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use

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

Barbiturates (BAR)

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death The approximate detection time limits for barbiturates are:

Short acting (e.g.Secobarbital) 100mgPO(oral) 4.5days Long acting(e.g.Phenobarbital) 400mgPO(oral) 7days

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

[ PRINCIPLE ]

The Multi-Drug Rapid Test Midstream for AMP /MET /COC /OPI /THC /PCP /MTD /MDMA /OXY /COT /KZ /BZO/KET/BAR 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

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, Δ9-THC-COOH, Phencyclidine, Methadone, Oxycodone, Cotinine, Barbiturates, Benzodiazepin es, Ketamine, 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.

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

[MATERIALS]

Test Midstream

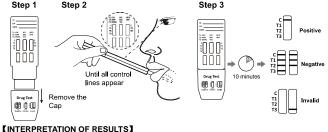
**Materials Provided**  Package insert Materials Required but Not Provided

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.

- Remove the test midstream from the sealed pouch and use it within one hour
- Insert the absorbent wick to the mouth and put it under the tongue to collect oral fluid until the control line appears Place the test midstream on a clean and level surface. See illustration below.
- Read results at 10 minutes. Do not read results after 15 minutes.



(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 indicates that the drug concentration is below the

\*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: A colored line appears in the Control region (C). No line appears in the test region (Drug/T). The positive result means that the drug concentration in the oral fluid sample is greater than the designated cut-off for a specific drug.

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 Midstream . 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.

- 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) or gas chromatography/tandem mass spectrometry (GC/MS/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
- 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 Midetream The results are summarized below

viidstream. The results are summanzed below.										
Drug conc.	n	AN	AMP		MTD		THC		ZO	
(Cut-off range)	- "	-	+	-	+	-	+	-	+	
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	27	3	25	5	27	3	25	5	
Cut-off	30	15	15	15	15	14	16	13	17	
+25% Cut-off	30	7	23	7	23	5	25	4	26	
+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.	n	PCP		COC		OPI		K2		BAR	
(Cut-off range)	"	-	+	-	+	-	+	-	+	-	+
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	25	5	27	3	26	4	27	3	28	2
Cut-off	30	14	16	15	15	15	15	13	17	20	10
+25% Cut-off	30	10	20	8	22	3	27	7	23	2	28
+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

Drug conc.	n	, MET		OXY		COT		MDMA		KET	
(Cut-off range)	n	-	+	-	+	-	+	-	+	-	+
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	25	5	26	4	25	5
Cut-off	30	16	14	20	10	20	10	19	11	18	12
+25% Cut-off	30	6	24	4	26	7	23	6	24	8	22
+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 /MDMA /OXY /COT /K2

/BZO/KET/BAR identified positive results at a read time of	
Compound	ng/mL
AMPHETAMINE (AMP)	
d-Amphetamine	50
d/l-Amphetamine	100
ß-Phenylethylamine	25,000
Tryptamine	12,500
p-Hydroxyamphetamine	100
(+)3,4-Methylenedioxyamphetamine (MDA)	100
I-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-Methylenedioxymethamphetamine (MDMA)	50
I-Phenylephrine (R)-(-)-Phenylephrine	6,250
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
Ephedrine	400
Benzphetamine	25,000
MARIJUANA (THC)	
11-nor-∆ <sup>9</sup> -THC-9 COOH	50
Cannabinol	50,000
Δ°-THC	25,000
Δ°-THC	40,000
11-nor-∆ <sup>8</sup> -THC-9 COOH	40
COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	30
Ecgonine	1,500
Ecgonine methyl ester	12,500
OPIATES (OPI)	
Morphine	40
Codeine	25
Ethylmorphine	25
Hydromorphine	100
Hydrocodone	100
Levorphanol	400

Oxycodone Morphine 3-β-D-Glucuronide	25,000
Morphine 3-β-D-Glucuronide	50
Norcodeine	6,250
Normorphine	25,000
Nalorphine	10,000
Ovymorphone	25,000
Oxymorphone Thebaine	2,000
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine	25
PHENCYCLIDINE (PCP)	
Phencyclidine	10
4-Hydroxyphencyclidine	2,500
METHADONE (MTD)	
Methadone	30
Disopyramide	400
(+)-Chlorpheniramine	6,250
LAAM	200
Doxylamine	
Nor-LAAM	12,500
OXYCODONE (OXY)	12,500
	loo
Oxycodone	20
Oxymorphone	40
Levorphanol	10,000
Hydrocodone	1,500
Hydromorphone	10,000
Naloxone	5,000
Naltrexone	5,000
COTININE (COT)	,0,000
(-)-Cotinine	20
COTININE (COT) (-)-Cotinine (-)-Nicotine	300
(-)-Nicourie	300
Methylenedioxymethamphetamine (MDMA)	IFO
(±) 3,4-Methylenedioxymethamphetamine HCI (MDMA)	50
(±) 3,4-Methylenedioxyamphetamine HCI (MDA)	300
3,4-Methylenedioxyethyl-amphetamine (MDE) I-Methamphetamine	30
I-Methamphetamine	25,000
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
IMIL 070 4 Ludroughutul metabolite	
JWH-073 4-Hydroxybutyl metabolite	250
Benzodiazepines (BZO)	
Alprazolam	15
a-hydroxyalprazolam	150
a-hydroxyalprazolam Bromazepam	75
Chlordiazepoxide	75
Clobazam	15
Clonazepam	40
Clorazepatedipotass	40
Delorazepam Desalkylflurazepam Disangam	75
Desolkulflurazonom	
Disancylliulazepaili Disances	15
Diazepani	150
Estazolam	600
Flunitrazepam	15
(±) Lorazepam RS-Lorazepamglucuronide	300
RS-Lorazepamglucuronide	15
Midazolam	600
Nitrazepam	15
Norchlordiazepoxide	15
Nordiazepam	75
Ovazenam	30
Oxazepam Temazepam	15
Trianglem	
Triazolam	300
Ketamine(KET)	Iso
Ketamine	50
Tetrahydrozoline	20
Benzphetamine d-Methamphetamine	1250
d-Methamphetamine	1250
(+)Chlorpheniramine	1250
I-Methamphetamine	2500
Clonidine Methoxyphenamine Discovered to	5000
Methoxynhenamine	625
Disopyramide	625
	625
d-Norpropoxyphene	
EDDP Davidada dina	2500
Pentazocine	1250
Mephentermine	1250
Phencyclidine	625
(1R, 2S) - (-)-Ephedrine	5000
Promazine	1250
4-Hydroxyphencyclidine	2500
Promethazine	1250
Levorphanol	2500
Thioridazino	2500
Thioridazine	
MDE	2500
Meperidine	1250
Dextromethorphan	75

(+)3,4-Methylendioxymethamphetamine (MDMA)	5000
Barbiturates (BAR)	<u> </u>
Amobarbital	833
5,5-Diphenylhydantoin	1333
Allobarbital	100
Barbital	1333
Talbutal	33
Cyclopentobarbital	5000
Pentobarbital	1333
Alphenol	100
Aprobarbital	83
Butabarbital	33
Butalbital	1333
Butethal	83
Phenobarbital	50
Secobarbital	50

### 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. d/I-Chloropheniramine Sulfamethazine Acetaminophen

> Tetracycline Tetrahydrocortisone 3

Thioridazine

Tolbutamide

Uric acid

Ketoprofen

Loperamide

Meprobamate

Nalidixic acid

Niacinamide

Noscapine

Oxalic acid

Penicillin-G

Perphenazine

hydrochloride

Prednisolone

Quinine

Zomepirac

d/I-Propranolol

d-Pseudoephedrine

Trans-2-phenylcyclopropylamine

Norethindrone

Oxymetazoline

Trifluoperazine

d/l-Tryptophan

(β-D-glucuronide)

N-Acetylprocainamide Aminopyrine Ampicillin Apomorphine Atropine Benzoic acid d/I-Brompheniramine Chloral-hydrate Chlorothiazide Chlorpromazine Cholesterol Cortisone Creatinine Dextromethorphan Diflunisal Diphenhydramine β-Estradiol

Ethyl-p-aminobenzoate

Hydrochlorothiazide

d/l-Isoproterenol

o-Hydroxyhippuric acid

Erythromycin

Furosemide

Hemoglobin

Ibuprofen

Estrone-3-sulfate I(-)-Epinephrine Fenoprofen Gentisic acid Hydralazine Hydrocortisone p-Hydroxytyramine Iproniazid İsoxsuprine Ketamine Labetalol

Chloroquine

Clonidine

I-Cotinine

Diclofenac

I-Ψ-Ephedrine

Digoxin

Deoxycorticosterone

Meperidine Methylphenidate Naproxen Nifedipine d-Norpropoxyphene d/I-Octopamine Oxolinic acid Papaverine

Acetophenetidin Acetylsalicylic acid Amoxicillin I-Ascorbic acid Aspartame Benzilic acid Benzphetamine Caffeine Chloramphenicol

Ranitidine Serotonin Sulindac Pentazocine hydrochloride Tetrahydrocortisone 3-acetate Phenelzine Thiamine Phenylpropanolamine d/I-Tyrosine Prednisone Triamterene d-Propoxyphene Trimethoprim Quinacrine Tyramine Verapamil

Quindine Salicylic acid

[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

McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201.

Attention see instructions for use For in vitro IVD diagnostic use only

Store between 2-30°C

Via Marconi, 1

20060 - Gessate (MI) Italy

Do not use if package is damaged Gima S.p.A.

Index of Symbols Tests per k Use by LOT Lot Numbe

Authorized EC REP Representative (2)Do not reuse Catalog #

EC REP MedNet GmbH Borkstrasse 10 48163 Muenster

Number: Effective date: 145384900 2016-10-08