Multi-Drug Saliva Rapid Screen Test Midstream

Package Insert

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, K2, Ketamine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Alcohol and their metabolites in human oral fluid.
For *in vitro* diagnostic use.

INTENDED USE

The **Multi-Drug Saliva Rapid Screen Test Midstream** is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, K2, Ketamine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Alcohol and their metabolites in oral fluids at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
Amphetamine (AMP)	D -Amphetamine	50 ng/mL
Barbiturates (BAR)	Secobarbital	50 ng/mL
Benzodiazepines (BZO)	Oxazepam	30 ng/mL
Benzodiazepines (BZO)	Oxazepam	50 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Cocaine	10 ng/mL
Cocaine (COC)	Cocaine	20 ng/mL
Cocaine (COC)	Cocaine	50 ng/mL
K2	JWH-018/JWH-073	50 ng/mL
Ketamine (KET)	Ketamine	100 ng/mL
Marijuana (THC)	THC-COOH	12 ng/mL
Marijuana (THC)	THC-COOH	25 ng/mL
Marijuana (THC)	THC-COOH	50 ng/mL
Methadone (MTD)	Methadone	35 ng/mL
Methamphetamine (mAMP/MET)	D-Methamphetamine	50 ng/mL
Methylenedioxymethamphetamine (MDMA)	Methylenedioxymethamphetamine	50 ng/mL
Methylenedioxymethamphetamine (MDMA)	Methylenedioxymethamphetamine	60 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Opiates (OPI)	Morphine	50 ng/mL
Opiates (OPI)	Morphine	300 ng/mL
Opiates (OPI)	Morphine	2000 ng/mL
Oxycodone (OXY)	Oxycodone	50 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Propoxyphene (PPX)	Propoxyphene	50 ng/mL
Alcohol (ALC)	Alcohol	≥0.05% B.A.C

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 AND EXPLANATION OF TEST

The **Multi-Drug Saliva Rapid Screen Test Midstream** for AMP/BAR/BZO/BUP/COC/K2/KET/THC/MTD/mAMP/MDMA/OPI/OXY/PCP/PPX/ALC and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument.

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 and up to 72 hours after use.

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. Only a small amount (less than 5%) of most barbiturates are excreted unaltered in the urine.

BENZODIAZEPINES (BZO)

Benzodiazepines are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex[fn], Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCI. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence.
Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

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

K2

Synthetic cannabis is a psychoactive herbal and chemical product that, when consumed, mimics the effects of cannabis. 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 cannabis product. The studies suggest that synthetic cannabinoid 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. As of March 1, 2011, five cannabinoids, JWH -018, JWH-073, CP-47, JWH-200 and cannabicyclohexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

KETAMINE (KET)

Ketamine is a drug used in human and veterinary medicine. Ketamine has a wide range of effects in humans, including analgesia, anesthesia, hallucinations and elevated blood pressure. Ketamine is primarily used for the induction and maintenance of general anesthesia, usually in combination with a sedative. The common way to abuse ketamine is smoking, inhalants, intravenous injection or drink. Ketamine is metabolized mostly into metabolites and only 5% of the prototype. The drug is metabolized quickly in the body, and usually can be detected within 2-3 hours after smoking.

MARIJUANA (THC)

Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), 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].

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). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

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.

METHAMPHETAMINE (mAMP / 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 and up to 72 hours after use.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2-3 hours.

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 dose'. 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is the major metabolic product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose.

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.

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/mL[4].

PROPOXYPHENE (PPX)

Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration.

ALCOHOL (ALC)

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since the urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine was set at 0.05%.

PRINCIPLE

① The **Multi-Drug Saliva Rapid Screen Test Midstream** is a competitive binding immunoassay in which drugs and drug metabolites in a oral fluid sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of oral fluid specimen is applied to the sample pad of the test device, the oral fluid specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the oral fluid specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

② Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue when contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry that uses the following highly specific enzymatic reaction:

$$CH_2CH_2OH + 0_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CH0 + H_20_2$$

$$H_20_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_20$$

During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (remains white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidaze to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive positive result for alcohol.

REAGENTS

① The **Multi-Drug Saliva Rapid Screen Test Midstream** contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against to Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, K2, Ketamine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine and Propoxyphene.

② Alcohol Test: The alcohol pad contains Tetramethylbenzidine, Alcohol Oxidaze, Peroxidase, Buffer and Stabilizing Proteins.

MATERIALS PROVIDED

- Drug Test Tube
- Product insert
- Procedure Card
- Oral fluid Collector
- Color chart for alcohol test (optional)

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- External positive and negative controls

PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use after the expiration date.
- The **Multi-Drug Saliva Rapid Screen Test Midstream** should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The test tube is for single use.
- The used collector and tube should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30℃. 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.

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 assay. Oral fluid collected at any time of the day may be used.

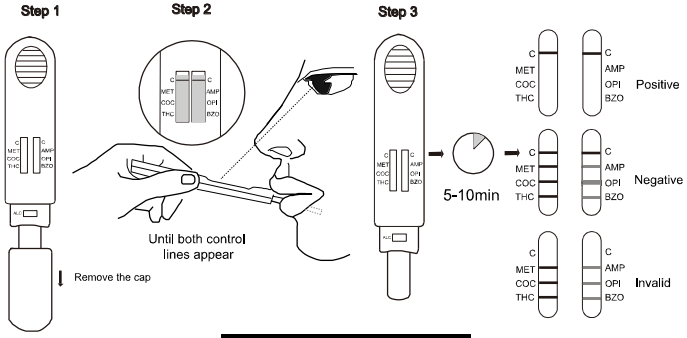
TEST PROCEDURE

Allow the test midstream specimen and/or control to reach room temperature [15-30℃ (59-86℉)] prior to testing. Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

1. Bring the pouch to room temperature before opening it, remove the test from the sealed pouch and use it within 1 hour.
2. Take off the Midstream cap and insert the absorbent wick to the mouth, put it under the tongue to collect oral fluid until the control line appears and then take out the midstream.

Note: Please refer to the illustrated operation below or keep the product level when you collect a saliva sample, otherwise it will lead to a wrong result.

3. Place the test midstream on a clean and level surface.
4. Read the drug test results at 5-10 minutes. Read the alcohol test result at 2 to 5 minutes. Do not read the results of drug tests after 1 hour, do not read the alcohol test result after 5 minutes.



INTERPRETATION OF RESULTS

Positive: One colored line appears in the Control zone (C). No line appears in the Test Zone (T). The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug level is above the detectable level.

Note: The samples with positive results should be confirmed with more specific method.

Negative: One colored line appears in the Control zone, and another colored line appears in the Test zone. The negative result indicates the drug or its metabolite level is below the detectable level.

Invalid: No line appears in the Control zone. If no C line or no C line and T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new test device. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new test strip or device. If the problem persists, discontinue using the current lot and contact your suppliers.

Alcohol Test Results

Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream color), it should be interpreted as a negative result (no alcohol present). A result where the outer edges of the alcohol pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be interpreted as negative (no alcohol present).

Alcohol Presumptive Positive Result: Blue or green color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.05% or higher.

QUALITY CONTROL

A procedure control is included in the test. A color 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 Saliva Rapid Screen 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.
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.
4. There is a possibility that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

PERFORMANCE CHAARACTERISTICS

Analytical Sensitivity

Sensitivity of **Multi-Drug Saliva Rapid Screen Test Midstream** was characterized by validating the test performance around the claimed cut-off concentration of each test. The cut-off of each test was determined by the lowest concentration of drug that produces at least 50% positive testing results in total numbers of determinations. 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 **Multi-Drug Saliva Rapid Screen Test Midstream**. The results are summarized below:

Drug concentration Cut-off Range	n	AMP		BAR		BZO 30		BZO 50		BUP		COC 10		COC 20	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-25% Cut-off	20	18	2	20	0	20	0	20	0	20	0	20	0	20	0
+25% Cut-off	20	0	20	4	16	0	20	0	20	2	18	0	20	7	13
+50% Cut-off	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	COC 50		K2		KET		THC 12		THC 25		THC 50		MTD	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0
+25% Cut-off	20	7	13	4	16	2	18	2	18	1	19	1	19	5	15
+50% Cut-off	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	mAMP		MDMA 50		MDMA 60		OPI 40		OPI 50		OPI 300		OPI 2000	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0	18	2
-25% Cut-off	20	20	0	20	0	20	0	13	7	13	7	15	5	12	8
+25% Cut-off	20	0	20	7	13	7	13	0	20	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	OXY		PCP		PPX	
		-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0
-25% Cut-off	20	15	5	20	0	20	0

+25% Cut-off	20	0	20	5	15	4	16
+50% Cut-off	20	0	20	0	20	0	20

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.05%, 0.08%, 0.30%). Negative saliva was used to test at 0% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the **Multi-Drug Saliva Rapid Screen Test Midstream** are summarized below:

Test	n	BAC (Concentration)							
		0%		0.05%		0.08%		0.30%	
	15	-	+	-	+	-	+	-	+
Alcohol	15	15	0	0	15	0	15	0	15

Analytical Specificity

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into Phosphate-buffered saline pool. Analyzing various concentration of each compound by using **Multi-Drug Saliva Rapid Screen Test Midstream**, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

Drug Compound	Concentration (ng/ml)
AMPHETAMINE (AMP)	
D-Amphetamine	50
D,LAmphetamine	125
L-Amphetamine	2500
(±)3,4-Methylenedioxyamphetamine (MDA)	100
Ephedrine	>10000
3,4-Methylenedioxythylamphetamine (MDEA)	>10000
BARBITURATES (BAR)	
Secobarbital	50
Phenobarbital	500
Butalbital	100
Pentobarbital	250
Amobarbital	500
Cyclopentobarbital	100
Butethal	125
Barbital	50
Butabarbital	250
BENZODIAZEPINES (BZO 30)	
Oxazepam	30
Alprazolam	40
α-Hydroxyalprazolam	250
Bromazepam	50
Chlordiazepoxide	500
Clobazam	20
Clonazepam	125
Clorazepate	50
Delorazepam	250
Diazepam	40
Estazolam	40
Flunitrazepam	50
Lorazepam	125
Midazolam	300
Nitrazepam	20
Nordiazepam	75
Temazepam	30
Triazolam	75
BENZODIAZEPINES (BZO 50)	
Oxazepam	50
Alprazolam	40
α-Hydroxyalprazolam	250
Bromazepam	50
Chlordiazepoxide	500
Clobazam	20
Clonazepam	125
Clorazepate	50
Delorazepam	250
Diazepam	40
Estazolam	40
Flunitrazepam	50
Lorazepam	125
Midazolam	300
Nitrazepam	20
Nordiazepam	75
Temazepam	30
Triazolam	75
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	15
Buprenorphine-3-D-glucuronide	12.5
Norbuprenorphine-3-D-glucuronide	175
Morphine-3-D-glucuronide	100000
Morphine	>100000
Oxymorphone	>100000
Hydromorphone	>100000
COCAINE (COC 10)	
Benzoylecogonine	10
Cocaine HCI	10
Cocaethylene	50
Ecgonine HCI	1500
COCAINE (COC 20)	
Benzoylecogonine	20
Cocaine HCI	20
Cocaethylene	50
Ecgonine HCI	1500
COCAINE (COC 50)	
Benzoylecogonine	50
Cocaine HCI	40
Cocaethylene	100
Ecgonine HCI	3000
K2	
JWH-018 N-(5-hydroxypentyl) metabolite	50
JWH-073 N-(4-hydroxybutyl) metabolite	50
JWH-018 pentanoic acid	50
JWH-073 butanoic acid	50
JWH-018	15,000
JWH-073	15,000
JWH 019 N-(5-hydroxyhexyl) metabolite	100
JWH 081 N-(5-hydroxypentyl) metabolite	3000
JWH 122 N-(5-hydroxypentyl) metabolite	150
JWH 200 5-hydroxyindole metabolite	150
JWH 203 N-(5-hydroxypentyl) metabolite	10000
JWH 210 N-(5-hydroxypentyl) metabolite	1500
JWH 250 N-(5-hydroxypentyl) metabolite	>100,000
JWH 398 N-(5-hydroxypentyl) metabolite	150
AM2201 N-(4-hydroxypentyl) metabolite	100
AM694 N-(5-hydroxypentyl) metabolite	250
PB-22 N-(5-hydroxypentyl) metabolite	>100,000
AKB48 N-(5-hydroxypentyl) metabolite	>100,000
KETAMINE (KET)	
Ketamine	100
methamphetamine	25,00
MARIJUANA (THC 12)	
11-nor-Δ^8-THC-9-COOH	12
11-nor-Δ^9-THC-9-COOH	12
Δ^8 -THC	2000
Δ^9 -THC	4000
Cannabinol	5000
Cannabidiol	10000
MARIJUANA (THC 25)	
11-nor-Δ^8-THC-9-COOH	25
11-nor-Δ^9-THC-9-COOH	25
Δ^8 -THC	1250
Δ^9 -THC	2250
Cannabinol	2500
Cannabidiol	5000
MARIJUANA (THC 50)	
11-nor-Δ^8-THC-9-COOH	50
11-nor-Δ^9-THC-9-COOH	50
Δ^8 -THC	2500
Δ^9 -THC	4500
Cannabinol	5000
Cannabidiol	10000

METHADONE (MTD)	
Methadone	35
Doxylamine	25000
METHAMPHETAMINE (mAMP/MET)	
D- Methamphetamine	50
3,4-Methylenedioxyethylamphetamine(MDEA)	1000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100
Ranitidine(Zantac)	>10000
3,4-Methylenedioxyamphetamine (MDA)	>10000
D-Amphetamine	>10000
L-Amphetamine	>10000
Ephedrine	>10000
Procaine	2000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 50)	
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	50
D-Amphetamine	>100000
L-Methamphetamine	100000
3,4-Methylenedioxyethylamphetamine (MDEA)	200
3,4-Methylenedioxyamphetamine (MDA)	2000
Oxycodone	1500
Oxymorphone	7500
Thebaine	2500
METHYLENEDIOXYMETHAMPHETAMINE (MDMA 60)	
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	60
D-Amphetamine	>100000
L-Methamphetamine	100000
3,4-Methylenedioxyethylamphetamine (MDEA)	200
3,4-Methylenedioxyamphetamine (MDA)	2000
OPIATES (OPI 40)	
Morphine	40
Codeine	40
Hydrocodone	250
Hydromorphone	250
Morphine 3-β-D-glucuronide	40
6-Monoacetylmorphine	80
Normorphone	10000
Oxycodone	1500
Oxymorphone	7500
Thebaine	2500
OPIATES (OPI 50)	
Morphine	50
Codeine	50
Hydrocodone	300
Hydromorphone	300
Morphine 3-β-D-glucuronide	50
6-Monoacetylmorphine	100
Normorphone	10000
OPIATES (OPI 300)	
Morphine	300
Codeine	300
Hydrocodone	1800
Hydromorphone	1800
Morphine 3-β-D-glucuronide	300
6-Monoacetylmorphine	600
Normorphone	10000
Oxycodone	1500
Oxymorphone	7500
Thebaine	2500
OPIATES (OPI 2000)	
Morphine	2000
Codeine	2000
Hydrocodone	12500
Hydromorphone	12500
Morphine 3-β-D-glucuronide	2000
6-Monoacetylmorphine	4000
Normorphone	500000
Oxycodone	75000
Oxymorphone	375000
Thebaine	125000
OXYCODONE (OXY)	
Oxycodone	50
Morphine	25000
Codeine	25000
Morphine 3-β-D-glucuronide	25000
Hydrocodone	1000
Hydromorphone	10000
Normorphone	10000
Oxymorphone	1000
PHENCYCLIDINE (PCP)	
Phencyclidine	10
4-Hydroxyphencyclidine	15000
Tetrahydrozoline	20000
PROPOXYPHENE (PPX)	
Propoxyphene	50
Norpropoxyphene	2500
Methadone	> 100000

Alcohol Test

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

Interfering Compounds

The following compounds in Phosphate-buffered saline pool with Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, K2, Ketamine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, and Propoxyphene, show no cross-reactivity when tested with **Multi-Drug Saliva Rapid Screen Test Midstream** at a concentration of 100 μg/mL.

Common Substances:

Acetaminophen	Diphenhydramine	(+/-)-Norephedrine
Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic Acid	Ethanol	Phenothiazine
Aspartame	Furosemide	1-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Theophylline
Creatine	(+)-Naproxen	Tyramine
Dexbrompheniramine	Niacinamide	4-Dimethylaminoantipyrine
Dextromethorphan	Nicotine	(1R,2S)-(-)-N-Methyl-Ephedrine

Alcohol Test

The following substances may interfere with the **Multi-Drug Saliva Rapid Screen Test Midstream** when using samples other than oral fluid:

1. Agents which enhance color development: Peroxides and strong oxidizers
2. Agents which inhibit color development:

Reducing Agents: such as Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptanalics and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methyldopa, L-dopa, L-methyldopa, and Methampyrone, etc. The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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GLOSSARY OF SYMBOLS

CE Approved

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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