Multi-Drug Rapid Test Cassette (Saliva tracer) (Oral Fluid)

Package Insert

English

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human saliva. Immunoassay for workplace and forensic use.

【INTENDED USE】

The Multi-Drug Rapid Test Cassette 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
Benzodiazepines (BZO)	Oxazepam	10
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	50
Methamphetamine (MET)	d-Methamphetamine	50
Methadone (MTD)	Methadone	30
Opiates (OPI/MOP)	Morphine	50
Oxycodone (OXY)	Oxycodone	40
Marijuana (THC)	Δ9-THC	15

This assay provides only a preliminary analytical test result. A more specific alternate chemical method should be used to confirm a non-negative analytical result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse screen test result, particularly when non-negative results are indicated.

【SUMMARY】

The Multi-Drug Rapid Test Cassette is a rapid saliva screening test that can be performed without the use of an instrument. The test utilises monoclonal antibodies to selectively detect elevated levels of specific drugs in human saliva.

Amphetamine (AMP)

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

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.

Buprenorphine(BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is soldunder the trade names Subutex™, Buprenex™, Temgesic™, and Suboxone™ which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is usedas 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[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].

Methamphetamine (MET)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use[1]. Methamphetamine can be detected in oral fluids for up to 72 hours after use[1].

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.

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 them intravenously or by nasal inhalation. Using an immunoassay cutoff level, 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[3]. The Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more commonly in its excreted unmetabolized form and is also the major metabolic product of codeine and heroin.

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 be metabolised by demethylation into oxymorphone and noroxycodone.

Marijuana (THC)

THC (Δ9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slow learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioural disorders.

The parent THC, also known as Δ9-THC, is present in oral fluid 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[5]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[5].

【ASSAY PRINCIPLE】

The Multi-Drug Rapid Test Cassette 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 the 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 a proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】

Each test line contains anti-drug antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】

- Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- Saliva is not classified as a biological hazard unless derived from a dental procedure.
- The used collector and cassette 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 cassettes 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 cassettes should be used with this assay. Oral fluid collected at any time of the day may be used.

【MATERIALS】

Materials Provided

- Test cassettes
- Package insert
- Procedure Card(when applicable)

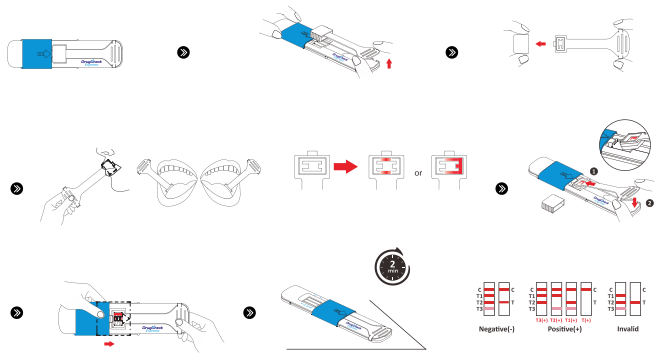
Materials Required but Not Provided

- Timer

【DIRECTIONS FOR USE】

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor not to 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. Remove the test from the sealed pouch and use within one hour of opening.
2. Instruct the donor to place the tongue against the root of the upper or lower jaw and collect saliva in the mouth.
3. Remove the swab from the cassette, then remove the cap from the swab.
4. Instruct the donor to place the swab between the lower cheek and gum and gently rub back and forth between the left and right cheeks and gums until the sponge is completely saturated with saliva. Do not bite, suck, or chew the sponge as it may break.
5. Remove the swab when two red/pink lines appear on the back of the swab or when the red/pink lines form a 3/4 turn, insert the swab into the cassette. If the saturation indicator has not turned red, place the swab back in the mouth and continue to collect saliva until the saturation indicator turns red.
   Note: When inserting the swab into the cassette, insert the protruding part of the swab head into the hole reserved at the sampling site, and then press down the tail of the swab to secure it.
6. Move the slider in the direction of the arrow until the slider is blocked.
7. Place the device on a flat surface while the test is running. Read the result at 2 minutes, if all lines are visible, the test can be interpreted as negative and discarded. If any results read positive at 2 minutes, then the results should be read at 5 minutes. Do not interpret results after 15 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the previous illustration)

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

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

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

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

【LIMITATIONS】

1. The Multi-Drug Rapid Test Cassette 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), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods.
2. A positive test result does not indicate the concentration of the 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】

Accuracy

Assemble each single test into the cassette before testing, and evaluate the cassette with approximately 44-280 specimens per drug type previously collected from subjects presenting for Drug Screen Testing, which were confirmed by GC/MS. These specimens were randomised and tested using the Oral Fluid Drug Screen Test. Specimens were rated as either positive or negative at 10 minutes. The test results are shown in table below.

Table: Specimen Correlation

Method		GC/MS		% agreement with GC/MS	% Total agreement with GC/MS
Multi-Drug Screen Test		Positive	Negative		
AMP50	Positive	90	6	94.7%	94.8%
	Negative	5	109	94.8%	
BZO10	Positive	94	5	94.0%	94.8%
	Negative	6	105	95.5%	
BUP10	Positive	86	5	95.6%	95.7%
	Negative	4	115	95.8%	
COC50	Positive	38	2	92.7%	96.7%
	Negative	3	107	98.2%	
MET 50	Positive	126	4	99.2%	98.2%
	Negative	1	149	97.4%	
MTD 30	Positive	116	3	97.5%	97.4%
	Negative	3	108	97.3%	
OPI 50	Positive	89	7	93.7%	93.8%
	Negative	6	108	93.9%	
OXY 40	Positive	93	0	>99.9%	>99.9%

	Negative	0	137	>99.9%	
THC 50	Positive	42	0	95.5%	97.8%
	Negative	2	48	>99.9%	

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 Cassette. The results are summarized below.

Drug conc. (Cut-off range)	n	AMP50		MET50		THC15		OXY40	
		-	+	-	+	-	+	-	+
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	28	2	27	3	25	5
Cut-off	30	15	15	16	14	12	18	15	15
+25% Cut-off	30	7	23	6	24	5	25	7	23
+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	BZO10		COC50		OPI50		BUP10	
		-	+	-	+	-	+	-	+
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	27	3
Cut-off	30	15	15	15	15	15	15	15	15
+25% Cut-off	30	7	23	3	27	8	22	7	23
+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	MTD30	
		-	+
0% Cut-off	30	30	0
-50% Cut-off	30	30	0
-25% Cut-off	30	25	5
Cut-off	30	15	15
+25% Cut-off	30	7	23
+50% Cut-off	30	0	30
+300% Cut-off	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the Multi-Drug Rapid Test Cassette identified positive results at a read time of 10 minutes.

Compound	ng/mL	Compound	ng/mL
AMPHETAMINE (AMP50)			
d-Amphetamine	50	p-Hydroxyamphetamine	100
D,L-Amphetamine	100	(+)3,4-Methylenedioxyamphetamine (MDA)	100
ß-Phenylethylamine	25,000	L -Amphetamine	4,000
Tryptamine	12,500	Methoxyphenamine	12,500
METHAMPHETAMINE (MET50)			
d-Methamphetamine	50	(1R,2S) - (-) Ephedrine	400
Fenfluramine	60,000	Procaine	2,000
p-Hydroxymethamphetamine	400	l-Phenylephrine (R)-(-)-Phenylephrine	6,250
Methoxyphenamine	25,000	Ephedrine	400
Mephentermine	1,500	Benzphetamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50	L-Methamphetamine	10,000
D,L - Methamphetamine	200		
MARIJUANA (THC15)			
Δ9 -THC	15	11- nor -Δ9-THC-9 COOH	12.5
Cannabinol	20,000	(-) Δ8 -THC	100
(±)-11-Hydroxy-Δ9-THC	400	(±) Δ8 -THC	40
COCAINE (COC50)			
Cocaine HCl	50	EcgonineHCl	37.5
Benzoylecgonine	50	Cocaethylene	75
OPIATES (OPI50)			
Morphine	50	Morphine 3-β-D-Glucuronide	90
Codeine	65	Normorphine	90,000
Ethylmorphine	65	Nalorphine	>100,000
Hydromorphine	250	Oxymorphone	65,000
Hydrocodone	150	Thebaine	35,000
Levorphanol	1,000	Diacetylmorphine (Heroin)	65
Oxycodone	75,000	6-Monoacetylmorphine	150
Levorphanol	10,000	Naloxone	5,000
Hydrocodone	1,500	Naltrexone	5,000
Hydromorphone	10,000	Thebaine	25,000
OXYCODONE (OXY40)			
Oxycodone	40	Codeine	50,000
Oxymorphone	80	Dihydrocodeine	12,500
Levorphanol	20,000	Naloxone	10,000
Hydrocodone	3,000	Naltrexone	10,000
Hydromorphone	20,000	Thebaine	50,000
BENZODIAZEPINES(BZO10)			
Oxazepam	10	7-Amino-clonazepam	5,000
Alprazolam	100	Bromazepam	10
Chlordiazepoxide	50	Clonazepam	1,000
BUPRENORPHINE(BUP10)			
Norbuprenorphine	180	Buprenorphine	10
Buprenorphine-3-β-D-glucuronide	100	Norbuprenorphine-3-β-D-glucuronide	600
METHADONE (MTD30)			
Methadone	30	LAAM	200
Disopyramide	400	Doxylamine	12,500
(+)-Chlorpheniramine	6,250	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 Cassette when tested at concentrations up to 100 μg/mL.

Acetaminophen	Creatine	Imipramine	Phenelzine
Acetone	Cyclobenzaprine	Isoproterenol hydrochloride	Phenothiazine
Acetophenetidin	Dextromethorphan	Isoxsuprine	β-Phenylethylamine
Aspirin	Diclofenac	Kanamycin	Quinacrine
Albumin	Dicyclomine	Ketoprofen	Quinidine
Amoxapine	Diflunisal	Labetalol	Ranitidine
Amoxicillin	Digoxin	Lidocaine	Riboflavin
Ampicillin	4-Dimethylaminoantipyrine	Lindane	Sodium chloride
Ascorbic acid	Diphenhydramine	Loperamide	Sulfamethazine
Aspartame	5,5-Diphenylhydantoin	Meperidine	Sulindac
Atropine	Dopamine	Metoprolol	Temazepam
Benzoic acid	(1R, 2S) - (-)-Ephedrine	Nalidixic acid	Tetracycline
Bilirubin	Erythromycin	(+)-Naproxen	Thiamine
(+/-) Brompheniramine	Ethanol (Except ALC)	Nimesulide	Thioridazine
Benzocaine	Etodolac	Norethindrone	Tolbutamide
Buspirone	Famprofazone	Noscapine	Trazodone
Caffeine	Fenoprofen	Niacinamide	Triamterene
Chloramphenicol	Fluoxetine Hydrochloride	Norephedrine	Trifluoperazine
Chloroquine	Gentisic acid	Orphenadrine	Trimethoprim
S- (+)-Chlorpheniramine maleate salt	D (+) Glucose	Oxalic acid	Trimipramine
Chlorpromazine	Guaiacol Glyceryl Ether	Oxymetazoline	Tyramine
Chlorprothixene	Hemoglobin	Papaverine	Uric acid
Cimetidine	Hydralazine	Pemoline	Verapamil
Clomipramine	Hydrochlorothiazide	Penicillin-G	Zomepirac
Clonidine	Hydroxyzine	Perphenazine	

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Index of Symbols

	Consult Instruction for use	Σ	Tests per kit		Do not reuse
2°C 30°C	Store between 2-30°C		Use by	REF	Catalog #
	Do not use if package is damaged	LOT	Lot Number		

Manufactured For: Royal Medical Supplies Pty Ltd,
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DrugCheck Express