SureScreen Diagnostics

Multi-Drug Rapid Test Cassette (SureSwab Rapid) (Oral Fluid) Package Insert

English

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human saliva. For healthcare professionals including professionals at point of care sites. Immunoassay for invitro diagnostic use only.

【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	20
Cocaine (COC)	Benzoylecgonine	20
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI/MOP)	Morphine	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 preliminary positive 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 preliminary positive 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 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[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.

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].

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 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[2]. Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin.

Marijuana (THC)

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 behavioral 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[3]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[3].

【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 coloured 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 coloured line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a coloured 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 coloured line will always appear at the control line region, indicating that 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 IgG polyclonal antibodies.

【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 government, 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

Materials Required but Not Provided

- Timer

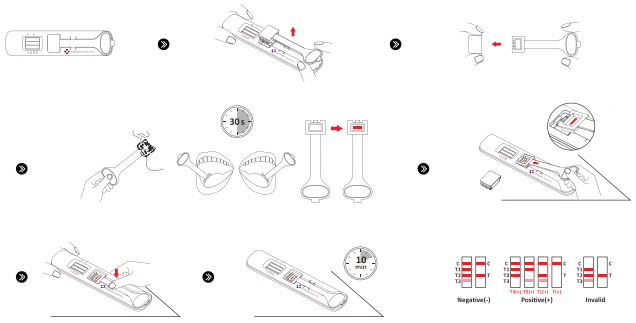
【DIRECTIONS FOR USE】

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening. Remove the test from the sealed pouch and use within one hour of opening.
2. Instruct the donor to place the tongue against bottom of the 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 force may cause it to break.
5. Remove the swab from the mouth after 30 seconds, if the saturation indicator on the back of the swab has turned red, insert the swab into the cassette. If the saturation indicator has not turned red, place the swab back into the mouth and continue to collect saliva until the saturation indicator turns red.
6. Insert the swab into the cassette.

Note: When inserting the swab into the cassette, keep the cassette right side up and horizontal on a flat surface, insert the protruding part of the swab head into the hole reserved at the sampling site, and then press down on the centre of the swab until hearing a "click".

7.Leave the device on a flat surface while the test is running. Negative results can be read as soon as clear lines form in both the C and T zones of the test. Read presumptive positive results at 10 minutes. Do not read results after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the previous illustration)

NEGATIVE*: Two lines appear. One coloured line should be in the control region (C), and another apparent coloured 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.

POSITIVE: One coloured line appears in the control region (C). No line appears in the test region (Drug/T). This positive 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 coloured 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 drug in the specimen or the route of administration.
3. A negative result may not necessarily indicate a drug-free specimen. Drugs 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 randomized 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%	
BZO20	Positive	94	5	94.0%	94.8%
	Negative	6	105	95.5%	
COC20	Positive	38	2	95.0%	96.7%
	Negative	3	107	97.3%	
MET 50	Positive	126	4	99.2%	98.2%
	Negative	1	149	97.4%	
OPI 40	Positive	89	7	93.7%	93.8%
	Negative	6	108	93.9%	
THC 15	Positive	43	0	95.6%	97.8%
	Negative	2	45	99%	

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		BZO20		COC20		MET50	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	30	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	26	4	25	5	28	2
Cut-off	30	15	15	14	16	15	15	16	14
+25% Cut-off	30	7	23	5	25	3	27	6	24
+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	OPI40		THC15	
		-	+	-	+
0% Cut-off	30	30	0	30	0
-50% Cut-off	30	30	0	30	0
-25% Cut-off	30	27	3	27	3
Cut-off	30	13	17	12	18
+25% Cut-off	30	7	23	5	25
+50% Cut-off	30	0	30	0	30
+300% Cut-off	30	0	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	25,000
Tryptamine	12,500	Methoxyphenamine	12,500
BENZODIAZEPINES (BZO20)			
Oxazepam	20	7-Amino-clonazepam	10,000
Alprazolam	200	Bromazepam	20
Chlordiazepoxide	100	Clonazepam	2,000
Desalkylflurazepam	1,000	Diazepam	100

Estazolam	160	Flunitrazepam	1,000
Furosemide	10,000	Lorazepam	1,400
Midazolam	2,000	Midazolam Maleate	5,000
Nefopam	2,000	Nitrazepam	50
Norchlordiazepoxide	50	Oxolinic acid	100,000
Pheniramine	100,000	Theophylline	100,000
α-Hydroxyalprazolam	100		
COCAINE (COC20)			
Cocaine HCl	20	EcgonineHCl	15
Benzoylecgonine	20	Cocaethylene	30
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		
OPIATES (OPI40)			
Morphine	40	Morphine 3-β-D-Glucuronide	70
Codeine	50	Normorphine	70,000
Ethylmorphine	50	Nalorphine	10,0000
Hydromorphine	200	Oxymorphone	50,000
Hydrocodone	100	Thebaine	25,000
Levorphanol	800	Diacetylmorphine (Heroin)	50
Oxycodone	60,000	6-Monoacetylmorphine	125
MARIJUANA (THC15)			
Δ9 -THC	15	11- nor -Δ9-THC-9 COOH	12.5
Cannabinol	20,000	(-) Δ8 -THC	100
(±)-11-Hydroxy-∆ 9-THC	400	(±) Δ8 -THC	40

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 with at concentrations up to 100 μg/mL.

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

【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”, *ClinChem,* 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 (1), pp 1-9

Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

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