For Forensic Use only

MD-S624 Oral Screen Saliva Drug Test

INTENDED USE

The Oral Screen Saliva Drug Test is a rapid visual immunoassay for the qualitative detection of drugs of abuse in human oral fluid specimens. The test system consists of up to 16 membrane strips mounted in a plastic device. This test detects combinations of the following drugs at the concentrations listed below. Specific combinations will vary according to the test in question:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	40
Barbiturate(BAR)	Secobarbital	50
Benzodiazepine (BZO)	Oxazepam	10/50
Buprenorphine(BUP)	Buprenorphine	5
Cocaine (COC)	Cocaine	20/30
Cotinine(COT)	Cotinine	50
EDDP(EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
K2	JWH-018/JWH-073	50
Ketamine (KET)	Ketamine	50
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	40/50
Ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine	50
Mephedrone（MEP）	Mephedrone	100
6-MAM	6-Monoacetylmorphine	25
Opiates (OPI)	Morphine	40
Opiates (OPI)	Morphine	25
Oxycodone(OXY)	Oxycodone	20/40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene(PPX)	Propoxyphene	50
Marijuana (THC)	11-nor-Δ^9-THC-9-COOH	12
Marijuana (THC parent)	Δ^9-THC	25
Marijuana (THC parent)	Δ^9-THC	50
FYL	Fentanyl	10
Alcohol（ALC）	Alcohol	0.02%/0.04% 0.08%/0.30%

PRINCIPLE

The Oral Screen Saliva Drug Test is an immunoassay based on the principle of competitive binding. Drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration in the oral fluid specimen will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Saliva Alcohol Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

MATERIALS

Materials Provided

- Individually packed screening devices
- Oral fluid collection swabs
- Package insert

Materials Required but Not provided

- Timer
- Positive and negative controls

PRECAUTIONS

- For Forensis Use Only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

STORAGE AND STABILITY

- The kit should be stored at 36-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

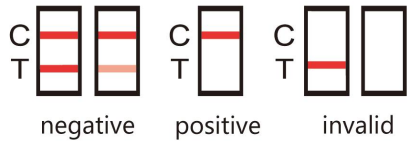
SPECIMEN COLLECTION AND STORAGE

- The Oral Screen Saliva Drug Test is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

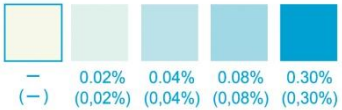
PROCEDURE

Bring tests, specimens, and/or controls to room temperature (60-86°F or 15-30°C) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

- The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay.
- Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.
- Bring tests, specimens, and/or controls to room temperature (60-86°F or 15-30°C) before use.
- Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, and tongue) several times, and then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. Important: Do not bite, suck, or chew on the sponge.
  NOTE: After 7 minutes, proceed with the test below, even if color on the saturation indicator has not appeared in the indicator window.
- Remove the collection swab from the mouth and insert it, sponge first, into the screening device. Screw cap down tightly until fully locked.
- Test device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Read results at 10 minutes. Do not interpret the result after 20 minutes.
- NOTE: Once the collection swab locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).



For ALC, read result at 3min，



Other Drug Tests，read result at 10min

INTERPRETATION OF RESULTS

- **INTERPRETATION OF DOA RESULTS:**

(See previous illustration)

POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

INVALID: Control band fails to appear. Results from any test which has not produced a control band (C) at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

For Alcohol tests:

Positive: The One Step Saliva Alcohol Test will produce a color change in the presence of saliva alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The One Step Saliva Alcohol Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% relative blood alcohol.

Negative: When the One Step Saliva Alcohol Test shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying saliva sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with saliva. The test is not reusable.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Oral Screen Saliva Drug Test is for forensis Use, and should be only used for the qualitative detection of drugs of abuse in oral fluid.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
5. A negative result does not at any time rule out the presence of drugs/metabolites in saliva, as they may be present below the minimum detection level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.

Limitation of ALC test:

1. Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
2. The Saliva Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Test. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

PERFORMANCE CHARACTERISTICS

A. Sensitivity

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 Oral Screen Saliva Drug Test. The results are summarized below.

Drug Conc.	n	AMP40		BUP5		BZO10		BZO50		COC20		COC30		COT50		EDDP20	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
75% Cutoff	30	30	0	28	2	30	0	30	0	28	2	29	1	30	0	30	0
Cutoff	30	12	18	11	19	14	16	8	22	11	19	12	18	11	19	13	17
125% Cutoff	30	2	28	8	22	4	26	3	27	4	26	2	28	1	29	2	28
150% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.	n	KET50		MET40		MET50		OPI25		OPI40		MTD30		MEP100		OXY20	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
75% Cutoff	30	27	3	30	0	30	0	26	4	28	2	30	0	2	28	30	0

Cutoff	30	9	21	13	17	13	17	13	17	10	20	10	20	8	22	11	19
125% Cutoff	30	3	27	3	27	3	27	6	24	9	21	2	28	4	26	5	25
150% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.	n	OXY40		PCP10		PPX50		THC12		THC25		THC50		MDMA50		FYL10	
(Cut-off)		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
Negative	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
75% Cutoff	30	28	2	28	2	30	0	30	0	30	0	30	0	25	5	22	8
Cutoff	30	10	20	11	19	10	20	10	20	10	20	10	20	14	16	12	18
125% Cutoff	30	4	26	5	25	4	26	5	25	2	28	4	26	4	26	2	28
150% Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc.	n	BAR50		6-MAM		K2 50	
(Cut-off)		-	+	-	+	-	+
Negative	30	30	0	30	0	30	0
50% Cut-off	30	30	0	30	0	30	0
75% Cutoff	30	27	3	30	0	26	4
Cutoff	30	9	21	15	15	10	20
125% Cutoff	30	3	27	2	28	4	26
150% Cutoff	30	0	30	0	30	0	30

B. Specificity

The following table lists the concentrations of compounds (in ng/ml) above which The Oral Screen Saliva Drug Test identified positive results at 10 minutes.

Amphetamine 40-Related Compounds

D-Amphetamine	40	Phentermine	30,000
L-Amphetamine	3,000	PMA	100
(+)-3,4-Methylenedioxyamphetamine (MDA)	120	Tyramine	2,500

Barbiturate 50-Related Compounds

Barbiturate (BAR)	50	Butalbital	400
Allobarbital	200	Butethal	30
Alphenal	100	Cyclopentobarbital	60
Amobarbital	100	Pentobarbital	150
Aprobarbital	30	Phenobarbital	300
Butabarbital	15		

Benzodiazepine 10-Related Compounds

Alprazolam	15	Lorazepam	20
Bromazepam	8	Medazepam	10
Chlordiazepoxide	10	Nitrazepam	10
Clonazepam	40	Nordiazepam	6
Clorazepate	20	Prazepam	20
Clbazam	6	Temazepam	8
Diazepam	15	Triazola	15
Estazolam	10	Desalkyflurazepam	8
Flurazepam	10	Flunitrazepam	10

Benzodiazepine 50-Related Compounds

Oxacepam	50	Flunitrazepam	50
Alprazolam	75	Flurazepam	50
Bromazepam	40	Lorazepam	100
Chlordiazepoxide	50	Medazepam	50
Clonazepam	200	Nitrazepam	50
Clorazepate	100	Nordiazepam	30
Clbazam	30	Prazepam	100
Diazepam	75	Temazepam	40
Estazolam	50	Triazola	75
Desalkyflurazepam	40		

Buprenorphine5 -Related Compounds

Buprenorphine	5	Norbuprenorphine	10
Buprenorphine Glucuronide	10	Norbuprenorphine–3–β–D–Glucuronide	200
Buprenorphine–3–β–D–Glucuronide	5		

Cocaine 20-Related Compounds

Cocaine	20	Ecgonine	100,000
Benzoylecgonine	200	Ecgonine methyl ester	10,000

Cocaine 30-Related Compounds

Cocaine	30	Ecgonine	>100000
Benzoylecgonine	300	Ecgonine methyl ester	30,000

Cotinine 50-Related Compounds

Cotinine	50	Buprenorphine	>100,000

EDDP 20 -Related Compounds

EDDP	20	Phencyclidine	20,000
Meperidine	20,000	Promazine	10,000
Methadone	20,000	Promethazine	5,000
Norfentanyl	20,000	Prothipendyl	10,000

Fentanyl 10-Related Compounds

Ketamine(KET)	50	D-Methamphetamine	＞10000
Norketamine	50	3,4-Methylenedioxyethylamphetamine (MDEA)	＞10000
Dextromethorphan	＞10000	Nordoxepin hy drochloride	＞10000
Dextrorphan tartrate	＞10000	Phencyclidine	＞10000
D-Norpropoxyphene	＞10000	Promazine	＞10000
Meperidine	＞10000	Promethazine	＞10000
Mephentemine hemisulfate salt	＞10000		

K2 50-Related Compounds

JWH-018-5 pentanoic	50	JWH-250 5-Hydroxypentyl	＞10000
JWH-073-4 Butanoic	50		

Ketamine 50-Related Compounds

Ketamine(KET)	50	D-Methamphetamine	＞100000
Norketamine	50	3,4-Methylenedioxyethylamphetamine (MDEA)	＞100000
Dextromethorphan		Phencyclidine	＞100000
D-Norpropoxyphene		Promethazine	＞100000
Meperidine			

Ecstasy 50-Related Compounds

3,4-Methylenedioxymethamphetamine(MDMA)	50	Paramethoxyamphetamine (PMA)	1,600
3,4-Methylenedioxyamphetamine (MDA)	250	Paramethoxymethamphetamine(PMMA)	160
3,4-Methylenedioxyethylamphetamine (MDEA)	60		

Methamphetamine 40-Related Compounds

D-Methamphetamine	40	3,4-Methylenedioxymethamphetamine (MDMA)	60
Fenfluramine	2,500	Mephentermine	150
L-Methamphetamine	400	PMMA	40
L-Phenylephrine	2,000	Procaine	2,000
MDEA	300		

Methamphetamine 50-Related Compounds

D-Methamphetamine	50	MDEA	400
Fenfluramine	3000	3,4-Methylenedioxymethamphetamine (MDMA)	75
L-Methamphetamine	500	Mephentermine	200
L-Phenylephrine	2500	PMMA	50
Procaine	2500		

MEP 100-Related Compounds

Mephedrone	100		

Methadone 30 -Related Compounds

Methadone	30	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)	10,000
Alpha-Methadol	125	Phencyclidine	12,500
Biperiden	80,000	Pheniramine	25,000
Doxylamine	12,500		

Marijuana25-Related Compounds

11-nor-Δ9 -THC-9 COOH	25	Δ9-Tetrahydrocannabinol	7,500
11-nor-Δ8 -THC-9 COOH	15	Cannabidiol	>10,000
Δ8-Tetrahydrocannabinol	7,500		

Marijuana 12-Related Compounds

11-nor-Δ9 -THC-9 COOH	12	Δ9-Tetrahydrocannabinol	4,000
Δ8-Tetrahydrocannabinol	2,000	11-hydroxy-Δ9 -THC	300

Marijuana 50-Related Compounds

Δ9-Tetrahydrocannabinol	50	11-hydroxy-Δ9 -THC	300
Δ8-Tetrahydrocannabinol	75	Cannabinol	2,000
11-nor-Δ9 -THC-9 COOH	12	Cannabidiol	>10,000

Opiates25 -Related Compounds

Morphine	25	Morphine-3- β-d-glucuronide	40
Codeine	8	Nalorphine	8,000
Diacetylmorphine (Heroin)	30	Oxycodone	15,000
Ethylmorphine	15	Oxymorphone	15,000
Hydrocodone	25	Thebaine	3,000
Hydromorphone	80	6-Monoacetylmorphine (6-MAM)	15

Opiates 40-Related Compounds

Morphine	40	Morphine-3- β-d-glucuronide	50
Codeine	50	Nalorphine	10,000
Diacetylmorphine (Heroin)	50	Oxycodone	25,000
Ethylmorphine	24	Oxymorphone	25,000
Hydrocodone	50	Thebaine	5,000
Hydromorphone	100	6-Monoacetylmorphine (6-MAM)	25

Oxycodone 20-Related Compounds

Oxycodone	20	Hydrocodone	500
Hydromorphone	3000	Naloxone	3000
Oxymorphone	20		

Oxycodone 40-Related Compounds

Oxycodone	40	Naloxone	6,250
Hydrocodone	1,000	Oxymorphone	40
Hydromorphone	6,250		

Propoxyphene 40-Related Compounds

Propoxyphene (PPX)	40	D-Norpropoxyphene	200

Phencyclidine 10-Related Compounds

Phencyclidine (PCP)	10	Morphine-3- β-d-glucuronide	20,000
Hydrocodone	2,000	Nalorphine	10,000
Hydromorphone	2,000		

Propoxyphene 50-Related Compounds

Propoxyphene (PPX)	50	D-Norpropoxyphene	200

6-MAM 10-Related Compounds

6-Monoacetylmorphine	10	Hydrocodone	>10,000
Acetylcodeine	>10,000	Hydromorphone	5,000
Buprenorphine	>10,000	Morphine	10,000
Codeine	>10,000	Morphine-3-glucuronide	>10,000
Diacetylmorphine	1000	Nalorphine	5,000
Dihydrocodeine	>10,000	Thebaine	>20,000
Ethylmorphine	>10,000		

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 Oral Screen Saliva Drug Test when tested at concentrations up to 100 ug/ml.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan (Except KET)	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate (Except KET)	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine

Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Imipramine	Trimeprazine
Bilirubin	(+/-)-Isoproterenol	Venlafaxine
b-Phenylethyl-amine	Methadone	Ibuprofen
Caffeine	Vitamin C (Ascorbic Acid)	Lidocaine
Chloroquine (Except MET)		

For ALC test:

The following substances may interfere with the Saliva Alcohol Test when using samples other than saliva. The named substances do not normally appear in sufficient quantity in saliva to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

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GLOSSARY OF SYMBOLS

ρ	Catalog number	ϐ	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	*In vitro* diagnostic medical device	ε	Use by
μ	Manufacturer	σ	Do not reuse