

MD-S616

Oral Screen Saliva Drug Test

For professional *in vitro* diagnostic use only.

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. 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)
6-MAM	6-Monoacetylmorphine	10
AMP	D-Amphetamine	50/40
BAR	Secobarbital	100/50
BZO	Oxazepam	100/50/10
BUP	Buprenorphine	5
COC	Cocaine	50/30/20
COT	Cotinine	50
EDDP	EDDP	20
FYL	Fentanyl	10
K2	JWH-073/JWH-018	50/30
K3	AB- PINACA	30
KET	Ketamine	100/50
MDMA	3,4-Methylenedioxymethamphetamine	50/40
MDPV	Methylenedioxypyrovalerone	50
MEP	Mephedrone	100
MET	D-Methamphetamine	50/40/35
MQL	Methaqualone	30
MTD	Methadone	50/30
OPI	Morphine	50/40/25/20
OXY	Oxycodone	40/20
PCP	Phencyclidine	10
PPX	Propoxyphene	50
TCA	Nortriptyline	300/100
THC(parent)	Δ^9 -Tetrahydrocannabinol	75/50/40/30/25
THC	11-nor- Δ^9 -THC-9 COOH	12
TML	Tramadol	30
ALC	Alcohol	0.02%/0.04%/0.08%/0.3%

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 professional *in vitro* diagnostic 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

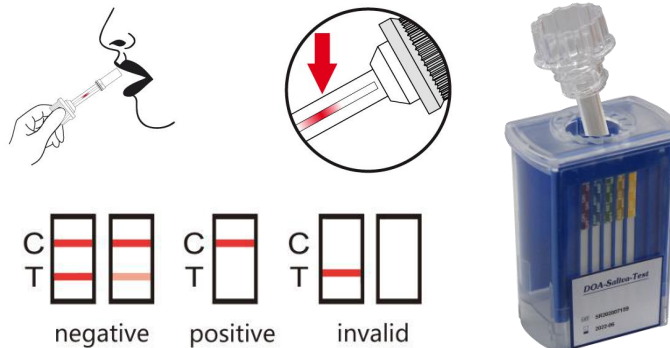
- The Oral Screen Saliva Drug Test is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, 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.
- For alcohol test, read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the alcohol concentration. Do not interpret the result after 3 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).



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.

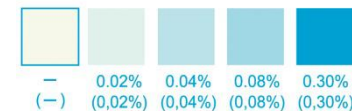
NEGATIVE: **Two colored bands appear** on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

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:

- 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.
- 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

- The Oral Screen Saliva Drug Test is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of drugs of abuse in oral fluid.
- 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 professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
- 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.
- A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
- 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.
- This test does not distinguish between drugs of abuse and certain medications.

Limitation of ALC test:

- 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.
- 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.
- 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. (Cut-off range)	n	6-MAM 10		AMP50		AMP 40		BAR100		BAR50		BZO100		BZO50	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	30	0	30	0	30	0	27	3	27	3	30	0	30	0
Cut-off	30	15	15	18	12	12	18	9	21	9	21	14	16	8	22
+25% Cut-off	30	2	28	2	28	1	29	2	28	3	27	4	26	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	BZO10		BUP5		COC50		COC30		COC20		COT50		EDDP20	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	30	0	28	2	30	0	29	1	29	1	30	0	30	0
Cut-off	30	14	16	11	19	10	20	12	18	12	18	11	19	13	17
+25% Cut-off	30	4	26	8	22	4	26	2	28	2	28	1	29	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	FYL10		K2 50		K2 30		K3 30		KET100		KET50	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	25	5	26	4	26	4	30	0	27	3	28	2
Cut-off	12	18	10	20	10	20	10	20	9	21	9	21
+25% Cut-off	8	22	3	27	4	26	1	29	3	27	3	27
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MDMA50		MDMA40		MDPV50		MEP100		MET50		MET40		MET35	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	30	30	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	30	30	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	22	8	20	10	30	0	30	0	30	0
Cut-off	30	14	16	14	16	10	20	8	22	13	17	9	21	8	22
+25% Cut-off	30	4	26	4	26	4	26	4	26	3	27	2	28	2	28
+50% Cut-off	30	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Drug Conc. (Cut-off range)	n	MQL30		MTD50		MTD30		OPI50		OPI40		OPI25		OPI20	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	12	18	30	0	30	0	27	3	28	2	26	4	26	4
Cut-off	30	14	16	8	22	10	20	9	21	10	20	13	17	13	17
+25% Cut-off	30	9	21	2	28	2	28	3	27	9	21	9	21	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off)	n	OXY40		OXY20		PCP10		PPX50		TCA 300		TCA 100		THC75	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	28	2	28	2	28	2	30	0	25	5	25	5	24	6
Cut-off	30	10	20	10	20	11	19	10	20	11	19	11	19	10	20
+25% Cut-off	30	4	26	4	26	5	25	4	26	6	24	6	24	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)		THC 50		THC40		THC30		THC25		THC 12		TML 30	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	
-25% Cut-off	30	0	30	0	30	0	24	6	30	0	10	20	

Cut-off	10	20	10	20	10	20	10	20	10	20	21	9
+25% Cut-off	4	26	5	25	5	25	8	22	5	25	15	15
+50% Cut-off	0	30	0	30	0	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.

6-MAM 10 Related Compounds		D-Methamphetamine	
6-Monoacetylmorphine	10	3,4-Methylenedioxyethylamphetamine (MDEA)	1,500
Acetylcodeine	>10,000	Nordoxepin hydrochloride	1,500
Buprenorphine	>10,000	Phencyclidine	250
Codeine	>10,000	Promazine	400
Diacetylmorphine	1000	Promethazine	1,250
Dihydrocodeine	>10,000	MDMA 50 Related Compounds	
Ethylmorphine	>10,000	3,4-Methylenedioxyamphetamin(MDMA)	50
Hydrocodone	>10,000	3,4-Methylenedioxyamphetamine (MDA)	250
Hydromorphone	5,000	3,4-Methylenedioxyethylamphetamine (MDEA)	60
Morphine	10,000	Paramethoxyamphetamine (PMA)	1,600
Morphine-3-glucuronide	>10,000	Paramethoxymethamphetamine(PMMA)	160
Nalorphine	5,000	MDMA 40 Related Compounds	
Thebaine	>20,000	3,4-Methylenedioxyamphetamin(MDMA)	40
AMP 50 Related Compounds		3,4-Methylenedioxyamphetamine (MDA)	200
D-Amphetamine	50	3,4-Methylenedioxyethylamphetamine (MDEA)	50
L-Amphetamine	4,000	Paramethoxyamphetamine (PMA)	1,200
(+)-3,4-Methylenedioxyamphetamine (MDA)	150	Paramethoxymethamphetamine(PMMA)	120
Phentermine	40,000	MDPV 50 Related Compounds	
PMA	125	3,4-Methylenedioxyprovalerone	50
Tyramine	3,000	Desmethyl Pyrovalerone HCl	3,000
AMP40 Related Compounds		Pyrovalerone	>100,000
D-Amphetamine	40	MEP 100 Related Compounds	
L-Amphetamine	3,000	Mephedrone	100
(+)-3,4-Methylenedioxyamphetamine (MDA)	120	MET 50 Related Compounds	
Phentermine	30,000	D-Methamphetamine	50
PMA	100	Fenfluramine	3,000
Tyramine	2,500	L-Methamphetamine	500
BAR 100 Related Compounds		L-Phenylephrine	2,500
Secobarbital	100	MDEA	400
Allobarbital	400	3,4-Methylenedioxyamphetamin(MDMA)	75
Alphenal	200	Mephentermine	200
Amobarbital	200	PMMA	50
Aprobarbital	60	Procaine	2,500
Butabarbital	30	MET 40 Related Compounds	
Butalbital	800	D-Methamphetamine	40
Butethal	60	Fenfluramine	2,500
Cyclopentobarbital	120	L-Methamphetamine	400
Pentobarbital	300	L-Phenylephrine	2,000
Phenobarbital	600	MDEA	300
BAR 50 Related Compounds		3,4-Methylenedioxyamphetamin(MDMA)	60
Secobarbital	50	Mephentermine	150
Allobarbital	200	PMMA	40
Alphenal	100	Procaine	2,000
Amobarbital	100	MET 35 Related Compounds	
Aprobarbital	30	D-Methamphetamine	35
Butabarbital	15	Fenfluramine	2800
Butalbital	400	L-Methamphetamine	500
Butethal	30	L-Phenylephrine	2500
Cyclopentobarbital	60	MDEA	300
Pentobarbital	150	3,4-Methylenedioxyamphetamin(MDMA)	50
Phenobarbital	300	Mephentermine	200
BUP 5 Related Compounds		PMMA	40
Buprenorphine	5	Procaine	2500
Buprenorphine Glucuronide	10	MTD 50 Related Compounds	
Buprenorphine-3-β-D-Glucuronide	5	Methadone	50

Norbuprenorphine	10	Alpha-Methadol	200
Norbuprenorphine-3-β-D-Glucuronide	200	Biperiden	100,000
BZO 100 Related Compounds		Doxylamine	20,000
Oxacepam	100	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidin e (EDDP)	15,000
Alprazolam	50	Phencyclidine	20,000
Bromazepam	500	Pheniramine	40,000
Chlordiazepoxide	100	MTD 30 Related Compounds	
Clobazam	50	Methadone	30
Clonazepam	1000	Alpha-Methadol	125
Clorazepat	100	Biperiden	80,000
Diazepam	100	Doxylamine	12,500
Estazolam	750	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidin e (EDDP)	10,000
Desalkylflurazepam	100	Phencyclidine	12,500
Midazolam	4000	Pheniramine	25,000
Nitrazepam	50	MQL 30 Related Compounds	
Norchlordiazepoxide	50	Methaqualone	30
Nordiazepam	150	OPI 50 Related Compounds	
Temazepam	75	Morphine	50
Triazolam	800	Codeine	15
Flurazepam	>10,000	Diacetylmorphine (Heroin)	60
Prazepam	>10,000	Ethylmorphine	30
Lormetazepam	500	Hydrocodone	60
BZO 50 Related Compounds		Hydromorphone	125
Oxacepam	50	6-Monoacetylmorphine (6-MAM)	60
Alprazolam	75	Morphine-3- β-d-glucuronide	60
Bromazepam	40	Nalorphine	12,500
Chlordiazepoxide	50	Oxycodone	31,250
Clonazepam	200	Oxymorphone	31,250
Clorazepate	100	Thebaine	6,250
Clbazam	30	OPI 40 Related Compounds	
Diazepam	75	Morphine	40
Estazolam	50	Codeine	50
Desalkylflurazepam	40	Diacetylmorphine (Heroin)	50
Flunitrazepam	50	Ethylmorphine	24
Flurazepam	50	Hydrocodone	50
Lorazepam	100	Hydromorphone	100
Medazepam	50	6-Monoacetylmorphine (6-MAM)	25
Nitrazepam	50	Morphine-3- β-d-glucuronide	50
Nordiazepam	30	Nalorphine	10,000
Prazepam	100	Oxycodone	25,000
Temazepam	40	Oxymorphone	25,000
Triazola	75	Thebaine	5,000
BZO 10 Related Compounds		OPI 25 Related Compounds	
Oxacepam	10	Morphine	25
Alprazolam	15	Codeine	8
Bromazepam	8	Diacetylmorphine (Heroin)	30
Chlordiazepoxide	10	Ethylmorphine	15
Clonazepam	40	Hydrocodone	25
Clorazepate	20	Hydromorphone	80
Clbazam	6	6-Monoacetylmorphine (6-MAM)	15
Diazepam	15	Morphine-3- β-d-glucuronide	40
Estazolam	10	Nalorphine	8,000
Desalkylflurazepam	8	Oxycodone	15,000
Flunitrazepam	10	Oxymorphone	15,000
Flurazepam	10	Thebaine	3,000
Lorazepam	20	OPI 20 Related Compounds	
Medazepam	10	Morphine	20
Nitrazepam	10	Codeine	50
Nordiazepam	6	Diacetylmorphine (Heroin)	50
Prazepam	20	Ethylmorphine	24
Temazepam	8	Hydrocodone	50

Triazola	15	Hydromorphone	100
COC 50 Related Compounds		6-Monoacetylmorphine (6-MAM)	25
Cocaine	50	Morphine-3- β-d-glucuronide	50
Benzoylcegonine	500	Nalorphine	10,000
Ecgonine	>100,000	Oxycodone	25,000
Ecgonine methyl ester	50,000	Oxymorphone	25,000
COC 30 Related Compounds		Thebaine	5,000
Cocaine	30	OXY 40 Related Compounds	
Benzoylcegonine	300	Oxycodone	40
Ecgonine	>100000	Hydrocodone	1,000
Ecgonine methyl ester	30,000	Hydromorphone	6,250
COC 20 Related Compounds		Naloxone	6,250
Cocaine	20	Oxymorphone	40
Benzoylcegonine	200	OXY 20 Related Compounds	
Ecgonine	100,000	Oxycodone	20
Ecgonine methyl ester	10,000	Hydrocodone	500
COT 50 Related Compounds		Hydromorphone	3,000
Cotinine	50	Naloxone	3,000
Buprenorphine	>100,000	Oxymorphone	20
EDDP 20 Related Compounds		PCP 10 Related Compounds	
EDDP	20	Phencyclidine (PCP)	10
Meperidine	20,000	Hydrocodone	2,000
Methadone	20,000	Hydromorphone	2,000
Norfentanyl	20,000	Morphine-3- β-d-glucuronide	20,000
Phencyclidine	20,000	Nalorphine	10,000
Promazine	10,000	PPX 50 Related Compounds	
Promethazine	5,000	Propoxyphene (PPX)	50
Prothipendyl	10,000	D-Norpropoxyphene	200
FYL 10 Related Compounds		TCA 100 Related Compounds	
Fentanyl	10	Nortriptyline	100
K2 50 Related Compounds		TCA 300 Related Compounds	
JWH-018 5-pentanoic	50	Nortriptyline	300
JWH-073 4-Butanoic	50	THC 75 Related Compounds	
K2 30 Related Compounds		Δ9-Tetrahydrocannabinol	75
JWH-018-5 pentanoic	30	Δ8-Tetrahydrocannabinol	150
JWH-073-4 Butanoic	30	11-nor-Δ9 -THC-9 COOH	30
JWH-250 5-Hydroxypentyl	>10,000	11-hydroxy-Δ9 -THC	500
K3 30 Related compounds		Cannabinol	20,000
AB- PINACA	30	Cannabidiol	>10,000
AB-PINACA 5-Pentanoic	30	THC 50 Related Compounds	
AB-PINACA 5-hydroxypentyl	30	Δ9-Tetrahydrocannabinol	50
AB- FUBINACA	50	Δ8-Tetrahydrocannabinol	75
AB-PINACA 4-hydroxypentyl	>10,000	11-nor-Δ9 -THC-9 COOH	12
UR-144 5-Pentanoic	5000	11-hydroxy-Δ9 -THC	300
UR-144	>10,000	Cannabinol	2,000
UR-144 5-hydroxypentyl	>10,000	Cannabidiol	>10,000
UR-144 4-hydroxypentyl	>10,000	THC parent 40 Related Compounds	
APINACA	>10,000	Δ9-Tetrahydrocannabinol	40
APINACA 5-hydroxypentyl	>10,000	Δ8-Tetrahydrocannabinol	75
ADB-PINACA N-(5-hydroxypentyl)	60	11-nor-Δ9 -THC-9 COOH	12
ADB-PINACA Pentanoic Acid	30	11-hydroxy-Δ9 -THC	300
5-fluoro AB-PINACA N-(4-hydroxypentyl)	60	Cannabinol	2,000
5-fluoro AB-PINACA	60	Cannabidiol	>10,000
KET 100 Related Compounds		THC 30 Related Compounds	
Ketamine(KET)	100	Δ9-Tetrahydrocannabinol	30
Norketamine	100	Δ8-Tetrahydrocannabinol	40
Dextromethorphan	50	11-nor-Δ9-THC-9 COOH	8
Dextrorphan tartrate	50	11-hydroxy-Δ9 -THC	150
D-Norpropoxyphene	3,000	Cannabinol	1,000
Meperidine	1500	Cannabidiol	>10,000
Mephentermine hemisulfate salt	2,000	THC 25 Related Compounds	
D-Methamphetamine	1500	Δ9-Tetrahydrocannabinol	25
3,4-Methylenedioxyethylamphetamine (MDEA)	3,000	Δ8-Tetrahydrocannabinol	60

Nordoxepin hydrochloride	3,000	11-nor-Δ9-THC-9 COOH	12
Phencyclidine	400	11-hydroxy-Δ9 -THC	300
Promazine	800	Cannabinol	2000
Promethazine	2,500	Cannabidiol	>10,000
KET 50 Related Compounds		THC 12 Related Compounds	
Ketamine(KET)	50	11-nor-Δ9 -THC-9 COOH	12
Norketamine	50	Δ8-Tetrahydrocannabinol	2,000
Dextromethorphan	25	Δ9-Tetrahydrocannabinol	4,000
Dextrorphan tartrate	25	11-hydroxy-Δ9 -THC	300
D-Norpropoxyphene	1,560	Tramadol 30-related compounds	
Meperidine	750	Tramadol	30
Mephentermine hemisulfate salt	1,000		

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 µg/mL.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan (Except KET)	Pheniramine
4-Dimethylaminoantirine	Dextrorphan tartrate (Except KET)	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline (Except TCA)	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Imipramine (Except TCA)	Trimeprazine
Bilirubin	(+/-)-Isoproterenol	Venlafaxine
b-Phenylethyl-amine	Methadone (Except MTD)	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
 - Methampryone

LITERATURE REFERENCES

- 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 FOFT-TIAFT meeting October 1998.
- Jenkins, A.J., Oyler, J.M. and Cone, E.J. Comparison of Heroin and Cocaine Concentrations in Saliva with Concentrations in Blood and Plasma. J. Anal. Toxicology. 19: 359-374 (1995).
- Kidwell, D.A., Holland, J.C., Athanaselis, S. Testing for Drugs of Abuse in Saliva and Sweat. J. Chrom. B. 713: 111-135 (1998).
- Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
- Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute of Drug Abuse; 1986.
- Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register;1988
- McBay AJ. Drug-analysis technology—pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (1 Suppl):33B-40B.
- Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman’s The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan;1980.

GLOSSARY OF SYMBOLS

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