MD-S341 Multi-drug Saliva Test Stick

INTENDED USE

The Multi-Saliva Drugs of Abuse Rapid Test Device is a rapid visual immunoassay for the qualitative, presumptive detection of drugs of abuse in human oral fluid specimens. The test system consists of one to three membrane strips mounted in a plastic cassette.
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-Monoacetylmorphine(6-MAM)	6-Monoacetylmorphine	25/10
Amphetamine (AMP)	D-Amphetamine	50/40
Barbiturate(BAR)	Secobarbital	50
Benzodiazepine (BZO)	Oxazepam	50/10
Buprenorphine(BUP)	Buprenorphine	5
Cocaine (COC)	Cocaine	50/30/20
Cotinine(COT)	Cotinine	50
Diazepam (DIA)	Diazepam	10
EDDP(EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrr olidine	20
Fentanyl(FYL)	Fentanyl	10
Ketamine（KET）	Ketamine	100/50
K2	JWH-073/JWH-018	50/30/25
Methamphetamine (MET)	D-Methamphetamine	50/40
Methaqualone (MQL)	Methaqualone	30
Ecstasy（MDMA）	3,4-Methylenedioxymethamphetamine	50/40
Methadone (MTD)	Methadone	50/30
Opiates (OPI)	Morphine	50/40/25
Oxycodone(OXY)	Oxycodone	40/20
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene(PPX)	Propoxyphene	50
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	25/12
Marijuana (THC)	Δ^9-THC	50/40
Tricyclic Antidepressant (TCA)	Nortriptyline	100
Tramadol (TML)	Cis-Tramadol	30
Alcohol（ALC）	Alcohol	0.02%

PRINCIPLE

The Multi-Saliva Drugs of Abuse Rapid Test Device 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 test devices
- Package insert
- Alcohol Color Chart (when applicable)

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.
- 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.

STORAGE AND STABILITY

- The kit should be stored at 2-30℃ 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.

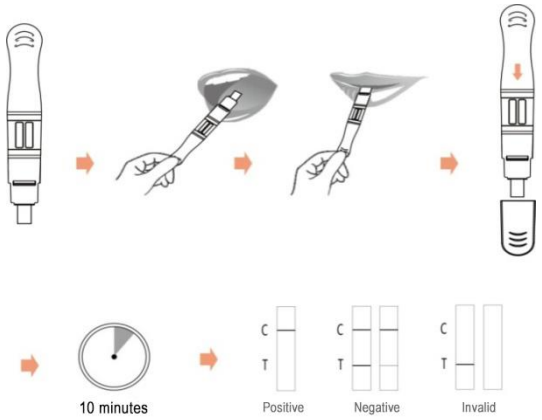
SPECIMEN COLLECTION AND STORAGE

- The Multi-Saliva Drugs of Abuse Rapid Test Device 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.

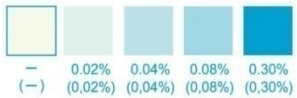
PROCEDURE

Bring tests, specimens, and/or controls to room temperature (15-30℃) 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.

1. Remove the cap by holding the sides and pulling gently. This will expose the collection pad.
2. Place the collection pad underneath the tongue to collect saliva. Instruct the donor to hold the device in place with hand.
3. Remove from mouth as soon as color move in both of the test windows. Re-cap the device.
   As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.



For ALC, read result at 3min，

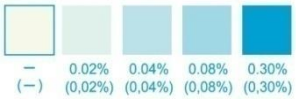


INTERPRETATION OF RESULTS

(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 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 Multi-Saliva Drugs of Abuse Rapid Test Device is for professional in vitro diagnostic use only, 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 professional 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 urine, 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 Multi-Saliva Drugs of Abuse Rapid Test Device. The results are summarized below.

Drug Conc. (Cut-off range)	n	6-MAM25		6-MAM10		AMP50		AMP40		BAR50		BZO50	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	27	3	27	3	25	5	29	1	27	3	24	6
Cut-off	30	11	19	10	20	12	18	10	20	9	21	8	22

+25% Cut-off	30	2	28	2	28	2	28	1	29	3	27	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	BZO10		BUP5		COC50		COC30		COC20	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	28	2	28	2	28	2	29	1
Cut-off	30	14	16	11	19	10	20	10	20	13	17
+25% Cut-off	30	4	26	8	22	4	26	2	28	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COT50		DIA10		EDDP20		FYL10		KET100		KET50	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	27	3	22	8	28	2	27	3	25	5	27	3
Cut-off	30	11	19	10	20	13	17	11	19	12	18	9	21
+25% Cut-off	30	1	29	5	25	2	28	4	26	4	26	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	K2 50		K2 30		K2 25		MET50		MET40		MQL30	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	28	2	19	11	27	3	26	4	25	5	12	18
Cut-off	30	8	22	10	20	10	20	13	17	12	18	14	16
+25% Cut-off	30	3	27	2	28	1	29	3	27	2	28	9	21
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MDMA50		MDMA40		MTD50		MTD30		OPI50		OPI40	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	25	5	25	5	28	2	26	4	27	3	28	2
Cut-off	30	14	16	13	17	8	22	10	20	9	21	10	20
+25% Cut-off	30	4	26	4	26	2	28	2	28	3	27	9	21
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	OPI25		OXY40		OXY20		PCP10		PPX50		THC50	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	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
-25% Cut-off	30	26	4	28	2	30	0	28	2	30	0	27	3
Cut-off	30	13	17	10	20	11	19	11	19	10	20	10	20
+25% Cut-off	30	9	21	4	26	5	25	5	25	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC40		THC25		THC12		TCA100		TML30	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	24	6	24	6	25	5	24	6
Cut-off	30	10	20	9	21	11	19	12	18	10	20
+25% Cut-off	30	5	25	7	23	7	23	6	24	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

B. Specificity

The following table lists the concentrations of compounds (ng/mL) above which the Multi-Saliva Drugs of Abuse Rapid Test Device identified positive results at 10 minutes.

6-MAM 10-Related Compounds

6-Monoacetylmorphine	10	Hydrocodone	>10,000
Acetylcodeine	>10,000	Hydromorphone	>100,000
Buprenorphine	>10,000	Morphine	100,000
Codeine	5000	Morphine-3-glucuronide	>10,000
Diacetylmorphine	1000	Nalorphine	>50,000
Dihydrocodeine	>10,000	Thebaine	>20,000
Ethylmorphine	>10,000		

6-MAM 25-Related Compounds

6-Monoacetylmorphine	25	Dihydrocodeine	50
Acetylcodeine	80	Ethylmorphine	15
Buprenorphine	>10000	Morphine-3-glucuronide	100
Codeine	15	Nalorphine	1200
Diacetylmorphine	15	Thebaine	>20000

AMP 40 -Related Compounds

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

AMP 50 -Related Compounds

D-Amphetamine	50	Phentermine	40,000
L-Amphetamine	4,000	PMA	125
(+)-3,4-Methylenedioxyamphetamine (MDA)	150	Tyramine	3,000

BAR 50 -Related Compounds

Secobarbital	50	Butalbital	400
Allobarbital	200	Butethal	30
Alphenal	100	Cyclopentobarbital	60
Amobarbital	100	Pentobarbital	150
Aprobarbital	30	Phenobarbital	300
Butabarbital	15		

BUP 5 -Related Compounds

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

BZO 10 -Related Compounds

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

BZO 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		

COC 20 -Related Compounds

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

COC 30 -Related Compounds

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

COC 50 -Related Compounds

Cocaine	50	Ecgonine	>100,000
Benzoylecgonine	500	Ecgonine methyl ester	50,000

COT 50 -Related Compounds

Cotinine	50	Buprenorphine	>100,000

DIA 10-Related Compounds

Diazepam	10	Estazolam	50
Oxazepam	450	Flurazepam	>50,000
Alprazolam	100	Flurazepam	250
Bromazepam	800	Lorazepam	10000
Chlordiazepoxide	1000	Nitrazepam	1000
Clobazam	50	Nordiazepam	100
Clonazepam	5000	Prazepam	100
Clorazepate	100	Temazepam	25
Desalkyflurazepam	1000	Triazolam	1000

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

FYL 10 -Related Compounds

Fentanyl	10		

K2 25 -Related Compounds

JWH-018 5-pentanoic	25	JWH-073 4-Butanoic	25

K2 30 -Related Compounds

JWH-018-5 pentanoic	30	JWH-250 5-Hydroxypentyl	>10,000
JWH-073-4 Butanoic	30		

K2 50 -Related Compounds

JWH-018 5-pentanoic	50	JWH-018 5-pentanoic	50

KET 50 -Related Compounds

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

KET 100 -Related Compounds

Ketamine(KET)	100	D-Methamphetamine	1500
Norketamine	100	3,4-Methylenedioxyethylamphetamine (MDEA)	3,000

Dextromethorphan	50	Nordoxepin hydrochloride	3,000
Dextrorphan tartrate	50	Phencyclidine	400
D-Norpropoxyphene	3,000	Promazine	800
Meperidine	1500	Promethazine	2,500
Mephentermine hemisulfate salt	2,000		

MDMA 40 -Related Compounds

3,4-Methylenedioxymethamphetamine(MDMA)	40	Paramethoxyamphetamine (PMA)	1,200
3,4-Methylenedioxyamphetamine (MDA)	200	Paramethoxymethamphetamine(PMMA)	120
3,4-Methylenedioxyethylamphetamine (MDEA)	50		

MDMA 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		

MET 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		

MET 50 -Related Compounds

D-Methamphetamine	50	3,4-Methylenedioxymethamphetamine (MDMA)	75
Fenfluramine	3,000	Mephentermine	200
L-Methamphetamine	500	PMMA	50
L-Phenylephrine	2,500	Procaine	2,500
MDEA	400		

MTD 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		

MTD 50 -Related Compounds

Methadone	50	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)	15,000
Alpha-Methadol	200	Phencyclidine	20,000
Biperiden	100,000	Pheniramine	40,000
Doxylamine	20,000		

MQL 30 -Related Compounds

Methaqualone	30

OPI 25 -Related Compounds

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

OPI 40 -Related Compounds

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

OPI 50 -Related Compounds

Morphine	50	6-Monoacetylmorphine (6-MAM)	60
Codeine	15	Morphine-3- β-d-glucuronide	60
Diacetylmorphine (Heroin)	60	Nalorphine	12,500
Ethylmorphine	30	Oxycodone	31,250
Hydrocodone	60	Oxymorphone	31,250
Hydromorphone	125	Thebaine	6,250

OXY 20 -Related Compounds

Oxycodone	20	Naloxone	3,000
Hydrocodone	500	Oxymorphone	20
Hydromorphone	3,000		

OXY 40 -Related Compounds

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

PCP 10 -Related Compounds

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

PPX 50 -Related Compounds

Propoxyphene (PPX)	50	D-Norpropoxyphene	200

TCA 100 -Related Compounds

Nortriptyline	100

THC 12 -Related Compounds

11-nor-Δ9 -THC-9 COOH	12	Δ 9-Tetrahydrocannabinol	4,000
Δ 8-Tetrahydrocannabinol	2,000	11-hydroxy-Δ9 -THC	300

THC 25 -Related Compounds

11-nor-Δ9-THC-9-COOH	25	Δ 9-Tetrahydrocannabinol	7,500
11-nor-Δ8-THC-9-COOH	15	Cannabinol	＞10000
Δ 8-Tetrahydrocannabinol	7,500		

THC parent 40 -Related Compounds

Δ 9-Tetrahydrocannabinol	40	11-hydroxy-Δ9 -THC	300
Δ 8-Tetrahydrocannabinol	75	Cannabinol	2,000
11-nor-Δ9 -THC-9 COOH	12	Cannabidiol	>10,000

THC parent 50 -Related Compounds

Δ 9-Tetrahydrocannabinol	50	11-hydroxy-Δ9 -THC	300
Δ 8-Tetrahydrocannabinol	75	Cannabinol	2,000
11-nor-Δ9 -THC-9 COOH	12	Cannabidiol	>10,000

TML 30 -Related Compounds

Tramadol	30

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-Saliva Drugs of Abuse Rapid Test Device when tested at concentrations up to 100ug/mL.

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate	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	Ibuprofen	Vitamin C (Ascorbic Acid)
Bilirubin	Imipramine	Trimeprazine
b-Phenylethyl-amine	Isoproterenol	Venlafaxine
Caffeine	Lidocaine	Ibuprofen
Chloroquine	Methadone (Except MTD)	

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

LITERATURE REFERENCES

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. 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

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer		Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

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