PRECISION

For Forensic use

MD-S620
Precision DX Saliva Drug Test

INTENDED USE

The Precision DX 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
Buprenorphine(BUP)	Buprenorphine	5
Cocaine (COC)	Cocaine	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
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	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	40
Alcohol（ALC）	Alcohol	0.02%/0.04% 0.08%/0.30%

PRINCIPLE

The Precision DXSaliva 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 isdamaged. Do not reuse tests.
- 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.

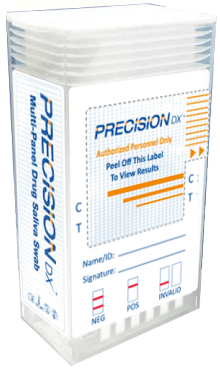
SPECIMEN COLLECTION AND STORAGE

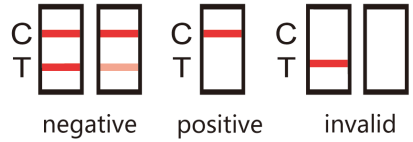
- The Precision DXSaliva Drug Test is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, 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 at least 3 minutes. Important: Do not bite, suck, or chew on the sponge.
- 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 3- 5 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 thatthe 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 Precision DX 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 Precision DXSaliva 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 Precision DXSaliva 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 Precision DX 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.
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 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. (Cut-off range)	n	AMP		BUP		BZO		COC	
		-	+	-	+	-	+	-	+
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	30	0	28	2	30	0	29	1
Cut-off	30	12	18	11	19	14	16	12	18
+25% Cut-off	30	2	28	8	22	4	26	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COT		EDDP		KET		MET	
		-	+	-	+	-	+	-	+
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	30	0	30	0	27	3	30	0
Cut-off	30	11	19	13	17	9	21	13	17
+25% Cut-off	30	1	29	2	28	3	27	3	27
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc.	n	MOR	MTD	MEP	OXY	PCP

(Cut-off range)		-	+	-	+	-	+	-	+	-	+
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	28	2	30	0	2	10	28	2	28	2
Cut-off	30	10	20	10	20	8	22	10	20	11	19
+25% Cut-off	30	9	21	4	26	4	26	4	26	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC		THC parent		BAR		PPX	
		-	+	-	+	-	+	-	+
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	30	0	30	0	27	3	30	0
Cut-off	30	10	20	10	20	9	21	10	20
+25% Cut-off	30	5	25	4	26	3	27	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	MDMA		6-MAM		MOR25		K2	
		-	+	-	+	-	+	-	+
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	25	5	30	0	26	4	26	4
Cut-off	30	14	16	15	15	13	17	10	20
+25% Cut-off	30	4	26	2	28	9	21	4	26
+50% Cut-off	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.

Amphetamine-Related Compounds	
D-Amphetamine	40
L-Amphetamine	4000
(+)-3,4-Methylenedioxyamphetamine	150
Phentermine	40000
PMA	125
Tyramine	3000
Barbiturate -Related Compounds	
Secobarbital	50
Allobarbital	200
Alphenal	100
Amobarbital	100
Aprobarbital	30
Butabarbital	15
Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	300
Benzodiazepine-Related Compounds	
Oxacepam	10
Alprazolam	15
Bromazepam	8
Chlordiazepoxide	10
Clonazepam	40
Clorazepate	20
Clbazam	6
Diazepam	15
Estazolam	10
Desalkyflurazepam	8
Flunitrazepam	10
Flurazepam	10
Lorazepam	20
Medazepam	10
Nitrazepam	10
Nordiazepam	6
Prazepam	20

Cotinine-Related Compounds	
Cotinine	50
Buprenorphine	>100000
EDDP -Related Compounds	
EDDP	20
Meperidine	20000
Methadone	20000
Norfentanyl	20000
Phencyclidine	20000
Promazine	10000
Promethazine	5000
Prothipendyl	10000
Ecstasy-Related Compounds	
3,4-Methylenedioxymethamphetamine	50
3,4-Methylenedioxyamphetamine	250
3,4-Methylenedioxyethylamphetamine	60
Paramethoxyamphetamine	1600
Paramethoxymethamphetamine	160
Methamphetamine-Related Compounds	
D-Methamphetamine	40
Fenfluramine	3000
L-Methamphetamine	500
L-Phenylephrine	2500
MDEA	400
3,4-Methylenedioxymethamphetamine	75
Mephentermine	200
PMMA	50
Procaine	2500
Mephedrone-Related Compounds	
Mephedrone	100
Opiates -Related Compounds	
Morphine	40
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	50
Hydromorphone	100

Temazepam	8
Triazola	15
Buprenorphine -Related Compounds	
Buprenorphine	5
Buprenorphine Glucuronide	10
Buprenorphine-3-β-D-Glucuronide	5
Norbuprenorphine	10
Norbuprenorphine-3-β-D-Glucuronide	200
Cocaine-Related Compounds	
Cocaine	30
Benzoylecgonine	200
Ecgonine	100000
Ecgonine methyl ester	10000
Prozine	2500
Ketamine-Related Compounds	
Ketamine(KET)	50
Norketamine	50
Dextromethorphan	25
Dextrorphan tartrate	25
D-Norpropoxyphene	1560
Meperidine	750
Mephenterminehemisulfate salt	1000
D-Methamphetamine	750
3,4-Methylenedioxyethylamphetamine	1500
Nordoxepin hydrochloride	1500
Phencyclidine	250
Promazine	400
Promethazine	1250
Marijuana -Related Compounds	
11-nor-Δ9 -THC-9 COOH	12
Δ8-Tetrahydrocannabinol	2000
Δ9-Tetrahydrocannabinol	4000
11-hydroxy-Δ9 -THC	300
Marijuana parent-Related Compounds	
Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	75
11-nor-Δ9 -THC-9 COOH	12
11-hydroxy-Δ9 -THC	300
Cannabinol	2000
Cannabidiol	>10000
Methadone -Related Compounds	
Methadone	50
Alpha-Methadol	125
Biperiden	80000
Doxylamine	12500
2-Ethylidene-1,5-dimethyl-3,3-diphenyl pyrolidine (EDDP)	10000
Phencyclidine	12500
Pheniramine	25000

6-Monoacetylmorphine (6-MAM)	25
Morphine-3- β-d-glucuronide	50
Nalorphine	10000
Oxycodone	25000
Oxymorphone	25000
Thebaine	5000
Opiates -Related Compounds	
Morphine	25
Codeine	8
Diacetylmorphine (Heroin)	30
Ethylmorphine	15
Hydrocodone	25
Hydromorphone	80
6-Monoacetylmorphine (6-MAM)	15
Morphine-3- β-d-glucuronide	40
Nalorphine	10000
Oxycodone	25000
Oxymorphone	25000
Thebaine	5000
Oxycodone-Related Compounds	
Oxycodone	40
Hydrocodone	1000
Hydromorphone	6250
Naloxone	6250
Oxymorphone	1000
Phencyclidine-Related Compounds	
Phencyclidine (PCP)	10
Hydrocodone	2000
Hydromorphone	2000
Morphine-3- β-d-glucuronide	20000
Nalorphine	10000
Propoxyphene -Related Compounds	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
6-MAM-Related Compounds	
6-Monoacetylmorphine	25
Acetylcodeine	80
Buprenorphine	>10000
Codeine	15
Diacetylmorphine	15
Dihydrocodeine	50
Ethylmorphine	15
Hydrocodone	600
Hydromorphone	600
Morphine	20
Morphine-3-glucuronide	100
Nalorphine	1200
Thebaine	>20000
K2(Spice) -Related Compounds	
JWH-018 5-pentanoic	50
JWH-073 4-Butanoic	50

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	GuaiacolGlyceryl 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

REF	Catalog number		Temperature limitation
☼	Consult instructions for use	…	Batch code
∩	*In vitro* diagnostic medical device	⧖	Use by
⫧	Manufacturer		Do not reuse

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