# **PRECISION**

For Forensic use

# Precision OralScan

### INTENDED USE

The Precision OralScan 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	10
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 <sup>9</sup> -THC-9-COOH	12
Marijuana (THC parent)	$\Delta^9$ -THC	40
Alcohol (ALC)	Alcohol	0.02%/0.04% 0.08%/0.30%

#### PRINCIPLE

The Precision OralScan 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 Forensic 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.

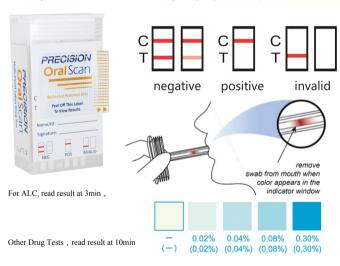
#### SPECIMEN COLLECTION AND STORAGE

- The Precision OralScan 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.

#### PROCEDURI

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).



#### INTERPRETATION OF RESULTS

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### (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.

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.

Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

#### For Alcohol tests:

Positive: The Precision OralScan 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 OralScan 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 Precision OralScan 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 Precision OralScan Saliva Drug Test is for Forensic 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).
- 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.
- 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.
- 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.
- 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  $\pm$  50% cut-off and  $\pm$  25% cut-off and tested with The Oral Screen Saliva Drug Test. The results are summarized below.

Γ	Drug Conc.		AM	ИP	Bl	JP	BZ	ZO.	CO	OC
	(Cut-off range)	n		+	ı	+	ı	+	ı	+
	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.	n	CO	TC	ED	DP	K	ET	M	ET
(Cut-off range)		-	+	-	+		+		+
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

P 0		1100	3.5000	3.650	OTITI
Drug Conc.	n	MOR	MTD	MEP	OXY

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(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.	n	TI	łС	THC	parent	BA	\R	PF	PΧ
(Cut-off range)	"	-	+	-	+	-	+	-	+
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.	n	MD	MA	6-M	AM	MO	R25	K	2
(Cut-off range)		-	+	-	+	-	+	-	+
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 comp

Saliva Drug Test identified positive results at 10 minut

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			

	28	9	21	4	26	
	30	0	30	0	30	
ınd	s (in ng	/ml) abo	ove whic	h The C	Oral So	creen
_	tinine-l	Related	Compou	ınds		
Сс	tinine				50	)
Βι	prenorp	hine			>1	10000
			ompoun	ds		
ΕI	DDP				20	)
M	eperidin	e			20	0000
M	ethadone	9			20	0000
No	orfentany	yl			20	0000
Ph	encyclic	line			20	0000
Pr	omazine	:			10	0000
Pr	omethaz	ine			50	000
Pr	othipend	lyl			10	0000
Еc	stasy-R	elated (	Compou	nds		
_				nphetam	ine 50	)
3,4	1-Methy	lenediox	yamphe	tamine	25	0
3,4	1-Methy	lenediox	yethylar	nphetam	ine 60	)
Pa	rametho	xyamph	etamine		16	500
Pa	rametho	xymetha	mphetar	nine	16	0
M	ethamp	hetamin	e-Relate	ed Comp	ound	s
D-	Metham	phetami	ne		40	)
Fe	nfluram	ine			30	000
L-	Metham	phetami	ne		50	00
L-	Phenyle	phrine			25	500
M	DEA				40	00
3,4	-Methy	lenediox	ymethan	nphetam	ine 75	j
M	ephenter	mine			20	0
PΝ	ИΜА				50	)
Pr	ocaine				25	00
M	ephedro	ne-Rela	ited Con	npounds	,	
M	ephedro	ne			10	0
Oı	piates -I	Related	Compou	nds		
M	orphine				40	)
Сс	deine				10	)
Di	acetylm	orphine	(Heroin)		50	)
Et	hylmorp	hine			24	
	drocodo				50	)
H	dromor	phone			10	00

Buprenorphine -Related Compounds	T <sub>e</sub>
Buprenorphine	5
Suprenorphine Glucuronide	10
Suprenorphine-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	
1-nor-Δ9 -THC-9 COOH	12
\alpha-Tetrahydrocannabinol	2000
\(\Delta\)-Tetrahydrocannabinol	4000
1-hydroxy-Δ9 -THC	300
Marijuana parent-Related Compound	ls
\Delta - \De	50
\\ 8-Tetrahydrocannabinol	75
1-nor-Δ9 -THC-9 COOH	12
1-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

Temazepam

Triazola

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.

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

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	s
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
6-MAM-Related Compounds	1
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

Acetone Erythromycin Protonix Albumin Ethanol Pseudoephedrine Amitriptyline Furosemide Quinidine Ampicillin Glucose Ranitidine Aspartame GuaiacolGlyceryl Ether Sertraline Aspirin Hemoglobin Tyramine Trimeprazine Benzocaine Imipramine Bilirubin Venlafaxine (+/-)-Isoproterenol b-Phenylethyl-amine Methadone Ibuprofen Caffeine Vitamin C (Ascorbic Acid) Lidocaine

Chloroquine (Except MET)

#### For ALC test:

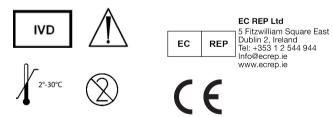
The following substances may interfere with the Saliva Alcohol Test when using samples other than saliva. The named substances do not normally appear in sufficient quantity in saliva to interfere with the test.

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

#### LITERATURE REFERENCES

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- 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 Use by Forensic use only medical device Manufacturer Do not reuse



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Customer Service Phone: 866-526-2873

Number: 1110022161

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