D-Pen' **Oral Fluid Drug Test**

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!



This package insert applies to any combination of multi-drug tests. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Please refer to the labels on the packaging and the prints on the test device to identify which drugs are included in your test.

D-Pen™ Oral Fluid Drug Test is a rapid oral fluid screening test. It's a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their principal metabolites in human oral fluid at the following cut-off concentrations.

Drug Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 40)	D-Amphetamine	40
Amphetamine (AMP 50)	D-Amphetamine	50
Barbiturates (BAR 20)	Secobarbital	20
Barbiturates (BAR 60)	Secobarbital	60
Benzodiazepines (BZO 10)	Oxazepam	10
Benzodiazepines (BZO 30)	Oxazepam	30
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC 20)	Cocaine	20
Cocaine (COC 50)	Cocaine	50
Cotinine (COT 20)	Cotinine	20
Cotinine (COT 50)	Cotinine	50
Cannabinoids (THC 12)	Δ9-THC	12
Cannabinoids (THC 40)	Δ9-THC	40
Cannabinoids (THC 50)	Δ9-THC	50
Fentanyl (FTY)	Norfentany l	20
Methadone (MTD)	Methadone	30
Methamphetamine (mAMP/MET)	D-Methamphetamine	50
Methylenedioxymethamphetamine (MDMA 25)	3,4-Methylenedioxymethamp- hetamine	25
Methylenedioxymethamphetamine (MDMA 50)	3,4-Methylenedioxymethamp- hetamine	50
Methylenedioxymethamphetamine (MDMA 100)	3,4-Methylenedioxymethamp- hetamine	100
Morphine (MOP)	Morphine	15
Opiate (OPI 15)	Morphine	15
Opiate (OPI 40)	Morphine	40

Opiate (OPI 50)	Morphine	50
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	25
6-Monoacetylmorphine(6-MAM 10)	6-Monoacetylmorphine	10
6-Monoacetylmorphine(6-MAM 15)	6-Monoacetylmorphine	15
6-Monoacetylmorphine(6-MAM 25)	6-Monoacetylmorphine	25
Alcohol (ALC)	Alcohol	>0.02% BAC

Configurations of the D-Pen™ Oral Fluid Drug Test can consist of any combination of the above listed drug analytes It is intended for forensic use only

This assay provides a qualitative preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary positive results are

SUMMARY

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion

Barbiturates (BAR)

Barbiturates are central nervous system (CNS) depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders

Buprenorphine (BUP)

Buprenorphine is a potent analogsic often used in the treatment of onioid addiction Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence.

Cocaine (COC)

Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating.

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that stimulates the autonomic ganglia and central nervous system in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. Aside from tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine qum, transdermal patches and nasal sprays. Regardless of whether nicotine in a donor was derived from tobacco use or through a nicotine-replacement therapy, if the metabolite cotinine is present in sufficient concentration, the test result will be positive.

Although nicotine is excreted in saliva, the relatively short half-life of the drug makes it an inreliable marker for tobacco use. Cotinine, however, demonstrates a substantially longer half-life than nicotine, bears a high correlation with plasma cotinine levels and has been found to be the best marker for smoking status compared with saliva nicotine measurements, breath carbon monoxide testing and plasma thiocyanate testing.

Cannabinoids (THC)

Cannabinoids is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor-Δ9-tetrahydro cannabinol-9-carboxylic acid with a half-life of 24 ours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired hort-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea

Fentanyl is an extremely fast-acting synthetic parcotic analgesic of high potency (approximately 100 to 200 times that of morphine) and short duration of action. Pharmaceutical fentanyl has been available since 1963 as an anaesthetic supplement and is available as a citrate salt for I.V or I.M injection. Transdermal patches are also available for management of chronic pain or for breakthrough cancer pain. Due to the linophilicity of the drug fentanyl rapidly crosses the blood-brain barrier producing fast and pronounced CNS effect, such as a heightened euphoria and respiratory depression, and possible toxic effects which include muscle rigidity, seizures, coma, and hypotension. Fentanyl also has similar tolerance and physical dependence properties to those of morphine.

Methadone (MTD)

Methadone is a narcotic analogsic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (Heroin, Vicodin, Percocet, morphine) The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use IV methadone acts more like oin. Methadone is a long-acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period.

Methamphetamine (mAMP/MET)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal

inhalation, smoking or oral ingestion

Methylenedioxymethamphetamine (MDMA)

MDMA is an abbreviation for the chemical methylenedioxymethamphetamine MDMA. It has street many names including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. It is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MOMA use include elevated blood pressure, hyperthermia, anxiety, paranoja, and insomnia Overdoses of MDMA can be fatal, often resulting in heart failure or heart stoke. MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the parent drug of MDMA, and MDEA (methylenedioxyethyl MDMA), also known as EVE. They all share the MOMA-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100 mg; the threshold toxic dose is 500mg. The effects of MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours, it is detectible in the saliva for up to 3 days after use.

Morphine (MOP) / Opiate (OPI)

The opiates such as heroin, morphine, and codeine are derived from the resin of opium poppy. The principal metabolites of opiates are morphine morphine 3-discurroride. normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized o morphine. Thus, morphine and morphine glucuronide might both be found in the saliva of a person who has taken only beroin. The body also changes codeine to morphine Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the saliva indicates heroin, morphine and/or codeine use. The window of detection varies for different opiates. Codeine can be detected within one hour and up to 7-21 hours after a single oral dose. Morphine is detectable for several days after a dose

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is nanufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycod like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues.

Phencyclidine (PCP)

Phencyclidine the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the

6-Monoacetylmorphine (6-MAM)

6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. 6-MAM remains in the urine for no more than 24 hours. So a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day, 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in urine virtually quarantees that heroin has recently been consumed.

Propoxyphene (PPX)

Propoxyphene is a narcotic analgesic with similar structure to methadone. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The United States Department of Transportation (DOT) has established a blood alcohol concentration (BAC) of 0.02% (20 mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

PRINCIPLE OF THE PROCEDURE

(1) Drugs of abuse test:

D-Pen™ Oral Fluid Drug Test is a competitive immunoassay that is used to screen for the presence of drugs in oral fluid. It is a chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combine to a limited number of oody-dye conjugate binding sites.

When the absorbent tip of the test device is immersed into the oral fluid sample the sample is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug/protein conjugate immobilized in the Test Region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result

When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a notentially positive result

To serve as a procedure control, a colored line will appear at the Control Region (C), if the

(2) Alcohol test:

Midazolam

Nitrazepam

Nordiazepam

Norchlordiazepoxi

The alcohol test device consists of a plastic strip with a reactive pad applied at the tip. The tip, on contact with solutions of alcohol, will rapidly turn shades of green to blue to coffee depending on the amount of alcohol present. The reactive pad employs a solid phase chemistry that is based on the high specificity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

The distinct color on reactive pad could be observed in less than 20 seconds after the tip was contacted with saliva samples with the ethyl alcohol concentration greater than 0.02%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in saliva.

WARNINGS AND PRECAUTIONS

- For external use only. Do not swallow.
- 2. Discard after first use. The test cannot be used more than once
- . Do not use the test kit beyond expiration date Do not use the test if the pouch is punctured or not well sealed.
- 5. Keep out of the reach of children
- Do not read result after 10 minute 7. The used test device should be discarded according to local regulations.

STORAGE AND STABILITY

- 1. Store at 35°F 86°F (2°C 30°C) in the sealed pouch up to the expiration date. 2. DO NOT FREEZE.
- . Keep away from direct sunlight, moisture and heat.
- 4. Preferably open the pouch only shortly before the test

MATERIALS AND COMPONENTS

REAGENTS AND MATERIALS SUPPLIED

- 25x D-Pen™ Oral Fluid Drug Tests 1x Color Chart for alcohol test interpretation (If equipped)
- 1x Instructions for use
- MATERIALS REQUIRED BUT NOT PROVIDED · Timer or stopwatch

SAMPLE COLLECTION AND TEST PROCEDURE

Please read the instructions carefully before testing.

- Allow the test device to equilibrate to room temperature (59°F 86°F / 15°C 30°C). 2. Remove the test device from the foil pouch by tearing at the notch. Hold the grip and remove the cap to expose the absorbent tip.
- 3. Place the absorbent tip horizontally into the mouth, then swab the inside of the mouth and tongue to collect oral fluid.
- 4. Take the absorbent tip out from the mouth when the purple color moves across the result window in the center of the device. 5. Immediately start the timer

6-1. Interpreting Alcohol Test Result:

Read result at 2 minutes, compare the reactive pad with the provided color chart. Do not read after 2 minutes.

6-2. Interpreting Drug Test Results:

Read results at 5 minutes. Do not read after 10 minutes

* When sampling, gently hold it in mouth and let oral fluid naturally adsorb on the absorbent tip. * Do not eat, drink, or smoke for at least 30 minutes prior to sample collection.

* Any oral fluid specimen is appropriate for testing but the oral fluid specimen collected in the morning, before mouth rinsed, eating or

INTERPRETATION OF TEST RESULTS

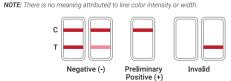
Preliminary Positive (+)

A color band is visible in each control region (C). If no color band appears in the appropriate drug test region, a positive result is indicated for the corresponding drug of that specific test region.

If a color band is visible in each control region (C) and the appropriate drug test region, it ndicates that the concentration of the corresponding drug of that specific test region is absent or below the detection limit of the test

Invalid

If a color band is not visible in the control region (C) or a color band is only visible in the drug test region, the test is invalid. Another test should be run to re-evaluate the



A distinct color is developed all over the pad. The positive result indicates that the BAC is 0.02% or higher. The alcohol concentration changes are related to the color chart below.



Almost no color changes compared to that of the background. A result where the outer edges of the reagent pad produce a slight color but the majority of the pad remains the background color should be repeated to ensure complete saturation of the reagent pad with saliva. If the second result is the same, the results should be interpreted as being negative. The negative result indicates that the BAC is less than 0.02%.

If the reaction pad has a green color before applying saliva sample, do not use this test.

QUALITY CONTROL

Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to onfirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

(2) Alcohol test:

ood Laboratory Practice recommends the daily use of control material to validate the reliability and stability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with

Alcohol test may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol alcohol into 8 oz of distilled water. This solution should show a distinct positive result. The color change indicates that the device has been properly filled and that the chemical reagents contained in the device are fully functional

LIMITATIONS OF PROCEDURE

- 1. A positive test result does not indicate the concentration of drug in the specimen or the
- 2. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the assay.
- 3. The alcohol test is highly sensitive to the presence of alcohol. Alcohol vapors in the air can sometimes be detected by the test. Alcohol is a component in many household products such as disinfectants, deodorizers, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of these vapors (such as

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity (1) For the drugs of abuse test

Standard drugs were diluted into the concentrations of -50% cut-off, -25% cut-off, cut-off, +25% cut-off and +50% cut-off. The results were summarized below

Drug Concentration	١	AMI	P 40	AMI	50	BAF	20	BAF	R 60	BZC	10	BZC	30
(Cut-off range)	n	•	+	-	+	-	+	-	+	•	+	•	+
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	28	2	26	4	29	1	27	3	26	4
Cut-off	30	17	13	12	18	10	20	12	18	16	14	13	17
+25% Cut -off	30	4	26	8	22	6	24	6	24	5	25	5	25
+50% Cut -off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration	_	BU	P 5	CO	C 20	CO	C 50	TH	C 12	TH	C 40	THO	50
(Cut-off range)	n	-	+	-	+	•	+	-	+	-	+	-	+
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	26	4	27	3	26	4	28	2	30	0
Cut-off	30	12	18	10	20	17	13	12	18	12	18	20	10
+25% Cut-off	30	3	27	6	24	3	27	6	24	5	25	6	24
+50% Cut -off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration		МТ	D 30	ME	T 50	MDN	1A25	MDN	1A50	MDM	IA100	OPI	15
(Cut-off range)	n	-	+	-	+	-	+	-	+	-	+	-	+
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	26	4	23	7	25	5	25	5	23	7
Cut-off	30	16	14	14	16	13	17	14	16	12	18	15	15
+25% Cut -off	30	8	22	5	25	6	24	6	24	5	25	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration		OPI	40	OP	50	МО	P 15	OX	Y 20	PCI	P 10	COT	Г 20
(Cut-off range)	n	-	+	-	+	-	+	-	+	-	+	-	+
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	29	1	28	2	26	4	28	2	24	6	25	5
Cut-off	30	10	20	10	20	12	18	12	18	14	16	17	13
+25% Cut -off	30	5	25	5	25	6	24	6	24	4	26	6	24
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration		CO	T 50	PP)	K 25	6-MA	M 10	6-MA	M 15	6-MA	M 25	FT\	20
(Cut-off range)	n	-	+	-	+	-	+	-	+	-	+	-	+
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	27	3	29	1	24	6	25	5	27	3
Cut-off	30	18	12	14	16	12	18	13	17	16	14	13	17
+25% Cut -off	30	5	25	5	25	6	24	6	24	6	24	5	25
+50% Cut -off	30	0	30	0	30	0	30	0	30	0	30	0	30

Oral fluid was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.02%, 0.08%, 0.30%). Negative oral fluid was used to test at 0.00% concentration. For each concentration, a total of 30 tests were performed to validate the test performance.

						B.A	A.C				
Test	n	0.0	0%	0.0	2%	0.0	5%	0.0	8%	0.3	0%
		-	+	-	+	-	+	-	+	-	+
Alcohol	30	30	0	0	30	0	30	0	30	0	30

Analytical Specificity

(1) For the Drugs of abuse test

The following table lists the concentration of compounds (ng/mL) above which the

Compound	Concentration (ng/mL)
Amphetamine (AMP 40)	
d-Amphetamine	40
d,FAmphetamine	100
ß-Phenylethylamine	3,200
Tryptamine	2,800
p-Hydroxyamphetamine	640
(+/-) 3,4-methylenedioxyamphetamine (MDA)	120
-Amphetamine	3,200
Amphetamine (AMP 50)	
d-Amphetamine	50
d,I-Amphetamine	125
ß-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+/-) 3,4-methylenedioxyamphetamine (MDA)	150
-Amphetamine	4,000

Amobarbital .	30
Alphenal	15
Aprobarbital	20
Butabarbital	10
Butatha l	10
Butalbital	250
Cyclopentobarbital	60
Pentobarbital	30
Phenobarbital Phenobarbital	10
Barbiturates (BAR 60)	
Secobarbital	60
Amobarbital	90
Alphenal	35
Aprobarbital	60
Butabarbital	30
Butathal	30
Butalbital	750
Cyclopentobarbital	180
Pentobarbital Pentobarbital	90
Phenobarbital	30
Benzodiazepines (BZO 10)	
Oxazepam	10
Alprazolam	6
Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
	100
Flunitrazepam	100

Butethal	30
Cyclopentobarbital	60
Pentobarbital Pentobarbital	150
Pentobarbital Pentobarbital	30
Benzodiazepines (BZO 30)	
Oxazepam	30
Alprazolam	20
Bromazepam	40
Chlordiazepoxide	40
Clobazam	20
Clorazepate	75
Delorazepam	75
Desalkylflurazepam	75
Diazepam	9
Estazolam	9
Flunitrazepam	300
a-Hydroxyalprazolam	600
(±)-Lorazepam	600
Midazolam	75
Nitrazepam	40
Norchlordiazepoxide	600
Nordiazepam	75
Temazepam	20
Triazolam	75
Butethal	90
Cyclopentobarbital	180
Pentobarbital Pentobarbital	450
Pentobarbital Pentobarbital	90
Buprenorphine (BUP 5)	
Buprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	10
Norbuprenorphine-3-D-Glucuronide	10
Cocaine (COC 20)	
Cocaine	20
Benzoylecgonine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
	12

Cocaine (COC 50)		
Cocaine	50	
Benzoylecgonine	50	
Cocaethylene	65	
Ecgonine	3,750	
Ecgonine methylester	31,250	
Cotinine (COT 20)		
(-) Cotinine	20	
S(-)-Nicotine	2.000	
S() NICOLINE	2,000	
Cotinine (COT 50)		
(-) Cotinine	50	
S(-)-Nicotine	5,000	
Cannabinoids (THC 12)		
11-nor-Δ9 -THC-9-COOH	12	
11-nor-Δ9-THC-9-COOH	7	
11-hydroxy-Δ9 -THC	600	
Δ8-THC	1,800	
Δ9-THC	2,400	
Cannabinol	24,000	
Cannabidiol	24,000	
Cannabidio	24,000	
Cannabinoids (THC 40)		
11-nor-Δ9 -THC-9-COOH	40	
11-nor-Δ8-THC-9-COOH	30	
11-hydroxy-Δ9 -THC	2,000	
Δ8-THC	7,500	
Δ9-THC	10,000	
Cannabinol	10,000	
Cannabidiol	100,000	
Cannabinoids (THC 50)		
11-nor-Δ9 -THC-9-C00H	50	
11-nor-Δ8-THC-9-COOH	30	
11-hydroxy-Δ9 -THC	2,500	
Δ8-THC	7,500	
Δ9-THC	10,000	
Cannabinol	10,000	
Cannabidiol	100,000	
	•	
Fentanyl 20 (FTY 20)		

lorfentany l	20
Fentanyl	200
Methadone (MTD 30)	
Methadone	30
Doxylamine	5,000
Methamphetamine (mAMP/MET 50)	
d-Methamphetamine	50
Fenfluramine	10.000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine(MDMA)	500
I-Phenylephrine	4,000
Procaine	2,000
(1R,2S)-(-) Ephedrine	400
Methylenedioxymethamphetamine (MD	MA 25)
3,4-Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
Methylenedioxymethamphetamine (MD	MA 50)
3,4-Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
Methylenedioxymethamphetamine (MD	MA 100)
3,4-Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
Opiate (OPI 15)	
Morphine	15
Codeine	15
Ethylmorphine	40
Heroin	15
Hydrocodone	90
Hydromorphine	40
Levorphanol	540
o-Monoacetylmorphine	40
Morphine 3-β-D-glucuronide	15
Norcodeine	90

Normorphone	400
Oxycodone	200
Oxymorphine	200
Procaine	1,125
Thebaine	750
Opiate (OPI 40)	
Morphine	40
Codeine	40
Ethylmorphine	100
Heroin	40
Hydrocodone	250
Hydromorphine	100
Levorphanol	1,500
σ-Monoacetylmorphine	100
Morphine 3-β-D-glucuronide	40
Norcodeine	250
Normorphone	1,000
Oxycodone	500
Oxymorphine	500
Procaine	3,000
Thebaine	2,000
Opiate (OPI 50)	
Morphine	50
Codeine	50
Ethylmorphine	125
Heroin	50
Hydrocodone	300
Hydromorphine	125
Levorphanol	1,800
σ-Monoacetylmorphine	125
Morphine 3-β-D-glucuronide	50
Norcodeine	300
Normorphone	1,250
Oxycodone	625
Oxymorphine	625
Procaine	3,750
Thebaine	2,500
Morphine (MOP 15)	
Morphine (MOP 15) Morphine	15
	15 15

Ethylmorphine	15	
Heroin	15	
Hydrocodone	250	
Hydromorphone	250	
Morphine 3-β-D-glucuronide	50	
σ-Monoacetylmorphine	20	
Oxycodone	1,250	
Oxymorphone	500	
Thebaine	1,500	
Oxycodone (OXY 20)		
Oxycodone	20	
Dihydrocodeine	4.000	
Codeine	10,000	
Hydromorphone	300,000	
Morphine	11,000	
Acetylmorphine	>10.000	
Buprenorphine	>10,000	
Ethy l morphine	>10.000	
Phencyclidine (PCP 10) Phencyclidine 4-Hydroxyphencyclidine	10 12,500	
Propoxyphene (PPX)		
d-Propoxyphene	25	
d-Norpropoxyphene	25	
	1	
6-Monoacetylmorphine (6-MAM 1	<u> </u>	
6-Monoacethylmorphine	10	
Codeine	10	
Ethylmorphine	200	
Hydrocodone	2,000	
Hydromorphone	100	
Levorphanol	50	
Morphine 3-β-D-glucuronide	30	
Morphine	10	
Norcodeine	200	
Normorphone	2,000	
Oxycodone	1,000	
Oxymorphone	2,000	
	500	
Procaine	300	

6-Monoacethylmorphine	15	
Codeine	15	
Ethylmorphine	300	
Hydrocodone	3,000	
Hydromorphone	150	
Levorphanol	75	
Morphine 3-β-D-glucuronide	45	
Morphine	15	
Norcodeine	300	
Normorphone	3,000	
Oxycodone	1,500	
Oxymorphone	3,000	
Procaine	750	
Thebaine	300	
6-Monoacethylmorphine	25	
Codeine	25	
Ethylmorphine Hydrocodone	500 5.000	_
Hydromorphone	250	—
Levorphanol	125	_
Morphine 3-β-D-glucuronide	75	—
Morphine Op D glacuroniae	25	_
Norcodeine	500	_
Normorphone	5,000	_
Oxycodone	2,500	_
Oxymorphone	5.000	_
Procaine	1,250	_
Thebaine	500	_

(2) For the alconol test Alcohol test will react with methyl, ethyl, and allyl alcohols. It will not react with alcohols having 5 or more carbons, nor with glycine, glycerol, or serine. This property is a result of the specificity of the alcohol oxidase. The following substances have been evaluated and do not interfere with the alcohol test at the concentration indicated.

Compound	Concentration (mg/dL)
Ethylene Glycol	20
Acetone	70
1-Propanol	10
2-Propanol	35

(1) For the drugs of abuse test

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with the following compounds. The following compounds show no cross-reactivity when tested with the D-Pen[™] Oral Fluid Drug Test at a concentration up to 100 μg/mL.

Aminopyrine	Lofexidine
Amoxici ll in	Loperamide
Ampici ll in	Maprotiline
Apomorphine	Meperidine
Aspartame	Meprobamate
Aspirin	Methadone (except MTD tests)
Atropine	Methoxyphenamine
Benadryl	Morphinie-3-b-d-glucuronide (except MOP, OPI tests)
Benzilic acid	N-Acetylprocainamide
Benzoic acid	Nalidixic acid
Benzoylecgonine (except COC test)	Naloxone
Bilirubin	Naltrexone
Cannabidiol (except THC test)	Naproxen
Captopril	Niacinamide
Chloralhydrate	Nifedipine
Chloramphenicol	Nitroglycerin
Chlorothiazide	Norcodeine (except MOP, OPI tests)
Chlorpromazine	Norethindrone
Chloroquine	Noscapine
Cholesterol	O-Hydroxyhippuric acid
Clarithromycin	Omeprazole
Clonidine	Oxalic acid
Codeine (except MOP, OPI, OXY tests)	Oxazepam (except BZO test)
(-) Cotinine (except COT test)	Oxolinic acid
Cortisone	Oxymetazoline
Creatinine	Papaverine
Deoxycorticosterone	Penici ll in V Potassium
Dextromethorphan	Penici ll in-G
Diazepam (except BZO test)	Pentobarbital (except BAR test)
Diclofenac	Perphenazine
Diflunisal	Phencyclidine (except PCP tests)
Digoxin	Phenelzine
Diphenhydramine	Phenytoin
D L-Tryptophan	Pholcodine
D,L-Isoproterenol	Prednisone
D,L-Octopamine	Procaine (except OPI, MOP tests)
DL-Propranolol	Propranolol HCI

DL-Tyrosine	Quinine
D-Norpropoxyphene (except PPX test)	Ranitidine
D-Propoxyphene (except PPX test)	Ranitidine HCI
D-Pseudoephedrine	Salicylic acid
Dopamine HCI	Secobarbital (except BAR test)
Doxepine	Serotonin (5-Hydroxytyramine)
Doxylamine (except MTD test)	Sulfamethazine
Ecgonine methyl ester	Sulindac
β-Estradiol	Tetrahydrocortisone3-(β-Dglucuronid
Erythromycin	Tetrahydrocortisone, 3-acetate
Estrogen	Tetrahydrozoline
Fenoprofen	Thiamine
Furosemide	Thioridazine
Gentisic acid	Triamterene
Hydralazine	Trif l uoperazine
Hydrochlorothiazide	Trimethoprim
Hydrocodone (except MOP, OPI tests)	Tyramine
3-Hydroxytyramine	Uric acid
Hydrocortisone	Venlafaxine HCI
Ibuprofen	Verapamil
Isoxsuprine	Sertraline Hydrochloride
Ketamine	Zomepirac
Ketoprofen	

(2) For the alcohol test
The following substances may interfere with the alcohol test:

Strong	oxidizers	Ascorbic acid
Tannic	acid	Polyphenolic compopunds
Mercap	tans	Uric acid
Bilirubir	ı	Oxalic acid

These compounds are not normally present in sufficient amount in saliva to interfere with the test. However, the precautions step must be taken so that these materials are not introduced into the mouth during the 10 minutes period proceeding to the test.

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4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201

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