

Amazewell™

D-Pen™ Oral Fluid Drug Test

INSTRUCTIONS FOR USE

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

REF See Box Label

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.

INTENDED USE

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)	Fentanyl	20
Methadone (MTD)	Methadone	30
Methamphetamine (mAMP/MET)	D-Methamphetamine	50
Methylenedioxyamphetamines (MDMA 25)	3,4-Methylenedioxyamphetamines	25
Methylenedioxyamphetamines (MDMA 50)	3,4-Methylenedioxyamphetamines	50
Methylenedioxyamphetamines (MDMA 100)	3,4-Methylenedioxyamphetamines	100
Morphine (MOP)	Morphine	15
Opiate (OPI 15)	Morphine	15
Opiate (OPI 40)	Morphine	40

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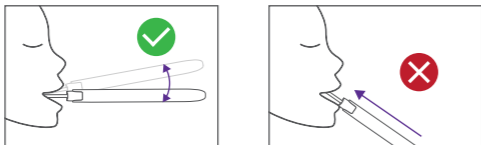
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WARNINGS AND PRECAUTIONS

- For external use only. Do not swallow.
- 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.
- Keep out of the reach of children.
- Do not read result after 10 minutes.
- The used test device should be discarded according to local regulations.



NOTE:

- * When sampling, gently hold it in mouth and let oral fluid naturally adsorb on the absorbent pad. Do not force saliva into the device to prevent flooding.
- * 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 drinking, is recommended.

INTERPRETATION OF TEST RESULTS

(1) Drug 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.

Negative (-)

If a color band is visible in each control region (C) and the appropriate drug test region, it indicates 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 specimen.

NOTE: There is no meaning attributed to line color intensity or width.



(2) Alcohol test results:

Positive (+)

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.

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 indicated.

SUMMARY

Amphetamine (AMP)

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 (BZO)

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

Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid 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 (COT)

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 gum, 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 unreliable 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-tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. 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 short-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 (FTY)

Fentanyl is an extremely fast-acting synthetic narcotic 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 IV or IM injection. Transdermal patches are also available for management of chronic pain or for breakthrough cancer pain. Due to the lipophilicity 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 analgesic 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 heroin. 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

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 (Cut-off range)	n	AMP 40	AMP 50	BAR 20	BAR 60	BZO 10	BZO 30
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	27	3	28	2	26	4
Cut-off	30	17	13	12	18	10	20
+25% Cut-off	30	4	26	8	22	6	24
+50% Cut-off	30	0	30	0	30	0	30

Drug Concentration (Cut-off range)	n	BUP 5	COC 20	COC 50	THC 12	THC 40	THC 50
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	28	2	26	4	27	3
Cut-off	30	12	18	10	20	17	13
+25% Cut-off	30	3	27	6	24	3	27
+50% Cut-off	30	0	30	0	30	0	30

Drug Concentration (Cut-off range)	n	MTD 30	MET 50	MDMA25	MDMA50	MDMA100	OPI 15
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	27	3	26	4	23	7
Cut-off	30	16	14	14	16	13	17
+25% Cut-off	30	8	22	5	25	6	24
+50% Cut-off	30	0	30	0	30	0	30

LIMITATIONS OF PROCEDURE

- A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
- 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.
- 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 outside).

inhalation, smoking or oral ingestion.

Methylenedioxyamphetamine (MDMA)

MDMA is an abbreviation for the chemical methylenedioxyamphetamine 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 cartoning 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, paranoia, 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 detectable 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-glucuronide, normorphine and codeine with a half-life of about 3 hours. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the saliva of a person who has taken only heroin. 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 manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, 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 oral cavity.

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 guarantees that heroin has recently been consumed.

Drug Concentration (Cut-off range)	n	OPI 40	OPI 50	MOP 15	OXY 20	PCP 10	COT 20
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	29	1	28	2	26	4
Cut-off	30	10	20	10	20	12	18
+25% Cut-off	30	5	25	5	25	6	24
+50% Cut-off	30	0	30	0	30	0	30

Drug Concentration (Cut-off range)	n	COT 50	PPX 25	6-MAM 10	6-MAM 15	6-MAM 25	FTY 20
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	26	4	27	3	29	1
Cut-off	30	18	12	14	16	12	18
+25% Cut-off	30	5	25	5	25	6	24
+50% Cut-off	30	0	30	0	30	0	30

(2) For the alcohol test

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.

Test	n	B.A.C					
		0.00%	0.02%	0.05%	0.08%	0.30%	
Alcohol	30	-	+	-	+	-	+
		0	0	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 D-Pen™ Oral Fluid Drug Test identified positive results at a read time of 5 minutes:

Compound	Concentration (ng/mL)
Amphetamine (AMP 40)	
d-Amphetamine	40
d,l-Amphetamine	100

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 (ALC)

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 antibody-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 potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

(2) Alcohol test:

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.

β-Phenylethylamine	3,200
Tryptamine	2,800
p-Hydroxyamphetamine	640
(+/-) 3,4-methylenedioxyamphetamine (MDA)	120
l-Amphetamine	3,200
Amphetamine (AMP 50)	
d-Amphetamine	50
d,l-Amphetamine	125
β-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+/-) 3,4-methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000

Barbiturates (BAR 20)	
Secobarbital	

Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
Flunitrazepam	100
a-Hydroxyalprazolam	200
(±)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
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

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Cyclopentobarbital	180
Pentobarbital	450
Pentobarbital	90
Buprenorphine (BUP 5)	
Buprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	10
Norbuprenorphine-3-D-Glucuronide	10
Cocaine (COC 20)	
Cocaine	20
Benzoyllecgonine	20
Cocacethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
Cocaine (COC 50)	
Cocaine	50
Benzoyllecgonine	50
Cocacethylene	65
Ecgonine	3,750
Ecgonine methylester	31,250

Cotinine (COT 20)	
(-) Cotinine	20
S(-)-Nicotine	2,000

Cotinine (COT 50)	
(-) Cotinine	50
S(-)-Nicotine	5,000
Cannabinoids (THC 12)	
11-nor-Δ ⁹ -THC-9-COOH	12
11-nor-Δ ⁸ -THC-9-COOH	7
11-hydroxy-Δ ⁹ -THC	600
Δ ⁸ -THC	1,800
Δ ⁹ -THC	2,400
Cannabinol	24,000
Cannabidiol	24,000

Cannabinoids (THC 40)	
11-nor-Δ ⁹ -THC-9-COOH	40

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11-nor-Δ ⁸ -THC-9-COOH	30
11-hydroxy-Δ ⁹ -THC	2,000
Δ ⁸ -THC	7,500
Δ ⁹ -THC	10,000
Cannabinol	10,000
Cannabidiol	100,000
Cannabinoids (THC 50)	
11-nor-Δ ⁹ -THC-9-COOH	50
11-nor-Δ ⁸ -THC-9-COOH	30
11-hydroxy-Δ ⁹ -THC	2,500
Δ ⁸ -THC	7,500
Δ ⁹ -THC	10,000
Cannabinol	10,000
Cannabidiol	100,000

Fentanyl 20 (FTY 20)	
Fentanyl	20
Carfentanyl	50
Sufentanyl	150
Alfentanyl	> 10,000
Norfentanyl	> 10,000
Buspirone	> 10,000

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-Methylenedioxyamphetamine(MDMA)	500
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)-(-)- Ephedrine	400

Methylenedioxyamphetamine (MDMA 25)	
3,4-Methylenedioxyamphetamine (MDMA)	25
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60

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Methylenedioxyamphetamine (MDMA 50)	
3,4-Methylenedioxyamphetamine (MDMA)	50
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60

Methylenedioxyamphetamine (MDMA 100)	
3,4-Methylenedioxyamphetamine (MDMA)	100
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60

Opiate (OPI 15)	
Morphine	15
Codeine	15
Ethylmorphine	40
Heroin	15
Hydrocodone	90
Hydromorphone	40
Levorphanol	540
α-Monoacetylmorphine	40
Morphine 3-β-D-glucuronide	15
Norcodeine	90
Normorphone	400
Oxycodone	200
Oxymorphone	200
Procaine	1,125
Thebaine	750

Opiate (OPI 40)	
Morphine	40
Codeine	40
Ethylmorphine	100
Heroin	40
Hydrocodone	250
Hydromorphone	100
Levorphanol	1,500
α-Monoacetylmorphine	100
Morphine 3-β-D-glucuronide	40
Norcodeine	250
Normorphone	1,000
Oxycodone	500
Oxymorphone	500
Procaine	3,000
Thebaine	2,000

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Opiate (OPI 50)	
Morphine	50
Codeine	50
Ethylmorphine	125
Heroin	50
Hydrocodone	300
Hydromorphone	125
Levorphanol	1,800
α-Monoacetylmorphine	125
Morphine 3-β-D-glucuronide	50
Norcodeine	300
Normorphone	1,250
Oxycodone	625
Oxymorphone	625
Procaine	3,750
Thebaine	2,500

Morphine (MOP 15)	
Morphine	15
Codeine	15
Ethylmorphine	15
Heroin	15
Hydrocodone	250
Hydromorphone	250
Morphine 3-β-D-glucuronide	50
α-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
Ethylmorphine	> 10,000

Phencyclidine (PCP 10)	
Phencyclidine	10
4-Hydroxyphencyclidine	12,500

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Propoxyphene (PPX)	
d-Propoxyphene	25
d-Norpropoxyphene	25

6-Monoacetylmorphine (6-MAM 10)	
6-Monoacetylmorphine	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
Procaine	500
Thebaine	200

6-Monoacetylmorphine (6-MAM 15)	
6-Monoacetylmorphine	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-Monoacetylmorphine (6-MAM 25)	
6-Monoacetylmorphine	25
Codeine	25
Ethylmorphine	500
Hydrocodone	5,000
Hydromorphone	250
Levorphanol	125

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Morphine 3-β-D-glucuronide	75
Morphine	25
Norcodeine	500
Normorphone	5,000
Oxycodone	2,500
Oxymorphone	5,000
Procaine	1,250
Thebaine	500

(2) For the alcohol 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

Cross-Reactivity**(1) For the drugs of abuse test**

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
Amoxicillin	Loperamide
Ampicillin	Maprotiline
Apomorphine	Meperidine
Aspartame	Meprobamate
Aspirin	Methadone (except MTD tests)
Atropine	Methoxyphenamine
Benadryl	Morphine-3-b-d-glucuronide (except MOP, OPI tests)
Benzilic acid	N-Acetylprocainamide
Benzoic acid	Nalidixic acid
Benzoyllecgonine (except COC test)	Naloxone
Bilirubin	Naltrexone
Cannabidiol (except THC test)	Naproxen
Captopril	Niacinamide
Chloralhydrate	Nifedipine
Chloramphenicol	Nitroglycerin
Chlorothiazide	Norcodeine (except MOP, OPI tests)

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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	Penicillin V Potassium
Dextromethorphan	Penicillin-G
Diazepam (except BZO test)	Pentobarbital (except BAR test)
Diclofenac	Perphenazine
Diflunisal	Phencyclidine (except PCP tests)
Digoxin	Phenelzine
Diphenhydramine	Phenytoln
D L-Tryptophan	Pholcodine
D,L-Isoproterenol	Prednisone
D,L-Octopamine	Procaine (except OPI, MOP tests)
DL-Propranolol	Propranolol HCl
DL-Tyrosine	Quinine
D-Norpropoxyphene (except PPX test)	Ranitidine
D-Propoxyphene (except PPX test)	Ranitidine HCl
D-Pseudoephedrine	Salicylic acid
Dopamine HCl	Secobarbital (except BAR test)
Doxepine	Serotonin (5-Hydroxytyramine)
Doxylamine (except MTD test)	Sulfamethazine
Ecgonine methyl ester	Sulindac
β-Estradiol	Tetrahydrocortisone3-(β-Dglucuronide)
Erythromycin	Tetrahydrocortisone, 3-acetate
Estrogen	Tetrahydrozoline
Fenoprofen	Thiamine
Furosemide	Thioridazine
Gentisic acid	Triamterene
Hydralazine	Trifluoperazine
Hydrochlorothiazide	Trimethoprim
Hydrocodone (except MOP, OPI tests)	Tyramine
3-Hydroxytyramine	Uric acid
Hydrocortisone	Venlafaxine HCl
Ibuprofen	Verapamil
Isosuprine	Sertraline Hydrochloride
Ketamine	Zomepirac
Ketoprofen	

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(2) For the alcohol test

The following substances may interfere with the alcohol test:

Strong oxidizers	Ascorbic acid
Tannic acid	Polyphenolic compopunds
Mercaptans	Uric acid
Bilirubin	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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ASSISTANCE

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INDEX OF SYMBOL

	Consult instructions for use		Keep dry
35°F 	Store at 35°F - 86°F (2°C - 30°C)		Keep away from sunlight
	Use-by date		Catalogue number
	Batch code		Do not reuse
	Do not use if package is damaged		

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Manufactured for:**Dochek USA INC**

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