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 print ons 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 for use in employment and insurance testing.

Drug Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	50
Barbiturates (BAR)	Secobarbital	20
Cocaine (COC)	Cocaine	20
Cannabinoids (THC)	Δ9-THC	40
Methadone (MTD)	Methadone	30
Methamphetamine (mAMP/MET)	D-Methamphetamine	50
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10

This assay provides only a qualitative, preliminary analytical test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

For employment and insurance testing use. For in vitro diagnostic use only.

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.

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.

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 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.

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 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, 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 detectible in the saliva for up to 3 days after use.

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.

PRINCIPLE OF THE PROCEDURE

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.

WARNINGS AND PRECAUTIONS

1. For external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use the test kit beyond expiration date.
4. Do not use the test if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read result after 10 minutes.
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.**
3. Keep away from direct sunlight, moisture and heat.
4. Preferably open the pouch only shortly before the test.

MATERIALS AND COMPONENTS

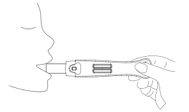
REAGENTS AND MATERIALS SUPPLIED
- 25x Dpen™ Oral Fluid Drug Tests
- 1x Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer or stopwatch

SAMPLE COLLECTION AND TEST PROCEDURE

Please read the instructions carefully before testing.

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



NOTE:
** 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 drinking, is recommended.*

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.

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.*

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 confirm 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.

LIMITATIONS OF PROCEDURE

1. The test provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. 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.

PERFORMANCE CHARACTERISTICS

A. Analytical Sensitivity

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	AMP50		BAR20		COC20		THC40		MTD30	
		-	+	-	+	-	+	-	+	-	+
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	26	4	26	4	28	2	27	3
Cut-off	30	12	18	10	20	10	20	12	18	16	14
+25% Cut-off	30	8	22	6	24	6	24	5	25	8	22
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Concentration (Cut-off range)	n	MET50		MDMA50		OPI 40		OXY20		PCP10	
		-	+	-	+	-	+	-	+	-	+
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	26	4	25	5	29	1	28	2	24	6
Cut-off	30	14	16	14	16	10	20	12	18	14	16
+25% Cut-off	30	5	25	6	24	5	25	6	24	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

B. Analytical Specificity

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)	
d-Amphetamine	50
dl-Amphetamine	125
ß-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+/-) 3,4-methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
Barbiturates (BAR)	
Secobarbital	20
Amobarbital	30
Alphenal	15
Aprobarbital	20
Butabarbital	10
Butathal	10
Butalbital	250

Cyclopentobarbital	60
Pentobarbital	30
Phenobarbital	10
Cocaine (COC)	
Cocaine	20
Benzoylecgonine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
Cannabinoids (THC)	
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
Methadone (MTD)	
Methadone	30
Doxylamine	5,000
Methamphetamine (mAMP/MET)	
d-Methamphetamine	50
Fenfluramine	10,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine(MDMA)	500
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)-(-) Ephedrine	400
Methylenedioxymethamphetamine (MDMA)	
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
Opiate (OPI)	
Morphine	40
Codeine	40
Ethylmorphine	100

Heroin	40
Hydrocodone	250
Hydromorphine	100
Levorphanol	1,500
o-Monoacetylmorphine	100
Morphine 3-β-D-glucuronide	40
Norcodeine	250
Normorphone	1,000
Oxycodone	500
Oxymorphine	500
Procaine	300
Thebaine	2,000
Oxycodone (OXY)	
Oxycodone	20
Dihydrocodeine	4,000
Codeine	10,000
Hydromorphone	300,000
Morphine	11,000
Acetylmorphine	＞10,000
Buprenorphine	＞10,000
Ethyl morphine	＞10,000
Phencyclidine (PCP)	
Phencyclidine	10
4-Hydroxyphencyclidine	12,500

C. 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
Amoxicillin	Loperamide
Ampicillin	Maprotiline
Apomorphine	Meperidine
Aspartame	Meprobamate
Aspirin	Methadone (except MTD tests)
Atropine	Methoxyphenamine
Benadryl	Morphinie-3-b-d-glucuronide (except 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 OPI tests)
Chlorpromazine	Norethindrone
Chloroquine	Noscapine
Cholesterol	O-Hydroxyhippuric acid
Clarithromycin	Omeprazole
Clonidine	Oxalic acid
Codeine (except OPI, OXY tests)	Oxazepam (except BZO test)
(-) Cotinine	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	Phenytoin
D L-Tryptophan	Pholcodine
D,L-Isoproterenol	Prednisone
D,L-Octopamine	Procaine (except OPI tests)
DL-Propranolol	Propranolol HCl
DL-Tyrosine	Quinine
D-Norpropoxyphene	Ranitidine
D-Propoxyphene	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 OPI tests)	Tyramine

3-Hydroxytyramine	Uric acid
Hydrocortisone	Venlafaxine HCl
Ibuprofen	Verapamil
Isoxsuprine	Sertraline Hydrochloride
Ketamine	Zomepirac
Ketoprofen	

BIBLIOGRAPHY OF SUGGESTED READING

1. Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
2. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9.
4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox. 1984 Sep-Oct.; 8 (5), pp 197-201

ASSISTANCE

Call toll-free ***(888) 695-5248*** (Monday – Friday 9:00 am – 5:00 pm, CST) or email to ***support@dochekusa.com.***

INDEX OF SYMBOL

Consult instructions for use	Keep dry
35°F 86°F — Store at 35°F - 86°F (2°C - 30°C)	Keep away from sunlight
Use-by date	REF — Catalogue number
LOT — Batch code	Do not reuse
IVD — *In vitro* diagnostic medical device	Do not use if package is damaged

Manufactured for:

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Made in China

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