

DOA PANEL TEST

FOR THE QUALITATIVE ASSESSMENT OF DRUGS AND THEIR METABOLITES IN HUMAN URINE

INTENDED USE

The DOA Panel Test is designed for qualitative determination of drug substances in human urine specimens. Below is a list of cut-off concentrations for each drug using our test.

Amphetamine	1000ng/ml
Barbiturate	300ng/ml
Benzodiazepines	300ng/ml
Cocaine	300ng/ml
Methamphetamine	1000ng/ml
Opiate	300ng/ml
Phencyclidine	25ng/ml
Cannabinoid	50ng/ml

The DOA Panel Test is available in combination of any of the above tests.

SUMMARY AND EXPLANATION

Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. The most common amphetamines are d-amphetamine and d,l-amphetamine. Amphetamines are central nervous stimulants that cause the neurotransmitters epinephrine, norepinephrine and dopamine to be released into the brain and body giving users feelings of euphoria, alertness, and increased energy. Chronic abuse of amphetamine leads to tolerance and drug reinforcement effect. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations and psychotic behavior. Amphetamine is metabolized by a number of pathways. In general, acid urine promotes excretion whereas alkaline urine retards it. In 24 hours, approximately 79% of the amphetamine dose is excreted in acid urine and about 45% in alkaline urine. Typically, about 20% is excreted as unchanged amphetamine. Unchanged amphetamine can be detected up to 1 –2 days after use.

Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induce exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effect of short-acting barbiturates such as secobarbital last 3 to 6 hours. The effects of long-acting barbiturates such as phenobarbital last 10 to 20 hours. Short-acting barbiturates normally remain detectable in urine for 4 to 6 days, while long-acting barbiturates can be detected for up to 30 days. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives, and glucuronide conjugates.

Benzodiazepines are a class of widely prescribed central nervous system depressants, which have anxiolytic, hypnotic, anticonvulsant and muscle relaxant effects. Chronic abuse can result in addiction and tardive dyskinesia. Acute higher doses lead to drowsiness, dizziness, muscle relaxation, lethargy, coma and possible death. The effects of benzodiazepines use last 4 – 8 hours. Many of the benzodiazepines share a common metabolic route, and are excreted as oxazepam and its glucuronide in urine. Oxazepam is detectable in the urine for up to 7 days after drug use.

Cocaine. Derived from the leaves of cocoa plant, cocaine is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological

effects induced by cocaine are: euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of cocaine could induce tolerances and physiological dependency, which leads to its abuse. Cocaine is used by smoking, intravenous, intranasal or oral administration and excreted in the urine primarily as Benzoylecgonine in a short period. Benzoylecgonine has a biological half-life of 5 – 8 hours, which is much longer than that of cocaine (0.5 – 1.5 hours), and can be generally detected for 12 – 72 hours after cocaine use or exposure.

Methamphetamine is the most popular synthetic derivative of the amphetamines. It is a potent sympathomimetic agent with therapeutic applications. Acute large doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-40% of methamphetamine is excreted unchanged. Methamphetamine is generally detectable in the urine for 3 to 5 days after use.

Opiate. Opioid analgesics comprised of a large group of substances that control pain by depressing the central nervous system. Acute high dose used by abusers or addicts can cause depressed coordination, disrupted decision, decreased respiration, hypothermia and coma. Morphine is excreted un-metabolized and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after opiates dose.

Phencyclidine, commonly known as PCP, is a hallucinogen, which interacts with dopamine, cholinergic and adrenergic systems. It has does dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high doses, from 100 to 500 ng/ml, PCP can cause convulsions, hypertension, prolonged coma, absent peripheral sensation, and even death. PCP is metabolized via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. About 10% of the dose is excreted in urine as unchanged drug. PCP can be detected in the urine for 7 to 8 days after drug administration. For chronic users, PCP may persist in urine for 2 to 4 weeks.

THC. The agents of Marijuana that cause various biological effects in humans are called cannabinoids. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoid could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. Δ^9 -THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor- Δ^9 -THC-9-COOH, which is found within hours of exposure and remains detectable in the urine for 3-10 days after smoking.

PRINCIPLE

Each strip on the DOA Panel test is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the

test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

MATERIAL PROVIDED

1. DOA Panel Test device.
2. Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Urine collection container.
2. Timer or clock.

STORAGE AND STABILITY

The test device should be stored at 2 to 30°C and will be effective until the expiration date.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. If the assay is not performed immediately, urine specimen may be refrigerated at 2° to 8°C up to 7 days or frozen. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Control standards can be used to validate reagent performance and establish test reliability. Controls, which are not provided with this test, are commercially available.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card and sealed foil pouch remove plastic cap.
3. Place the sample pad end into the urine specimen being careful to hold each pad in the urine **without touching the plastic card.**
4. Hold the card in the urine for 10 seconds, remove from the urine and replace the cap.
5. Read the result at 5 minutes.

Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Negative:

Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative

result does not indicate the absence of drug in the specimen; it only indicates that the amphetamine level in the specimen is less than cut-off level.

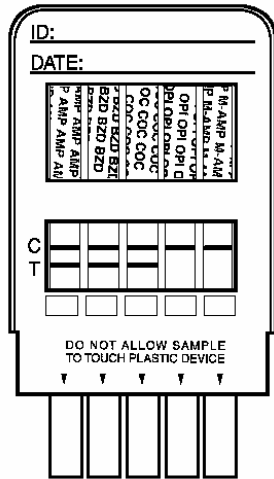
Positive:

One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the amphetamine level in the specimen is above the cut-off level.

Invalid:

If there is no colored band in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A very faint colored band in test line zone indicates that the amount of amphetamine in the sample is near the cut-off level. These specimens and any positive samples should be confirmed by and alternate method such as GC/MS.



This example here shows:

Positive for OPI and MAMP
Negative fro AMP, BZD, and COC.

EXPECTED RESULTS

The DOA Panel Test is a qualitative assay. It identifies the drug in human urine at its cut-off concentration or higher. The concentration of the drug cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

PERFORMANCE CHARACTERISTICS

Sensitivity

Test	Compounds	Cut-off (ng/ml)	Cross Reactivity (%)
Amphetamine	Amphetamine	1,000	100
	d,l-Amphetamine	2,000	50
	(±)3,4Methylenedioxyamphetamin	2,500	40
	e l-Amphetamine	30,000	3.3

Barbiturate	Secobarbital	300	100
	Alphenal	100	300
	Amobarbital	300	100
	Barbital	150	200
	Butalbital	5000	6
	Pentobarbital	150	200
	Phenobarbital	150	200
Benzodiazepine	Nitrazepam	100	300
	Chlordiazepoxide HCl	300	100
	Clobazam	300	100
	Desmethyldiazepam	300	100
	Oxazepam	300	100
	Temzepam	300	100
	Alprazolam	1000	30
	Bromazepam	1000	30
	Diazepam	1000	30
	Flunitrazepam	1000	30
	Lorazepam	1000	30
	Clonazepam	2000	15
	Flurazepam	100	0
	Cocaine	Benzoyllecgonine	300
Cocaine		30,000	1.0
Methamphetamine	(+)Methamphetamine	1000	100
	(±)3,4Methylenedioxyamphetamin	1000	100
Opiate	Morphine	300	100
	Morphine-3-β-glucuronide	300	100
	Codeine	300	100
	Hydromrphone	300	100
	Nalorphine	750	40
	Heroin	1250	24
	Hydrocodone	1250	24
	Normorphine	2000	15
	Norcodeine	2500	12
	Naloxone	25,000	1.2
	Natrexone	100,000	0.3
Phencyclidine	PCP	25	100
Cannabinoid	11-nor-Δ ⁹ -THC-9-COOH	50	100
	11-nor-Δ ⁸ -THC-9-COOH	37.5	133
	11-hydroxy-Δ ⁹ -THC	5000	1
	Δ ⁸ -Tetrahydrocannabinol	15000	0.33
	Δ ⁹ -Tetrahydrocannabinol	25000	0.20

Acetaminophen	4-Acetamidophenol
Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital
Arterenol	Aspartame
Ascorbic acid	Atrophine
Caffeine	Camphor
Chloroquine	Chlopheniramine
Cortisone	Deoxyephedrine
Dextromethorphan	Digitoxin
Digoxin	Diphenhydramine
Ecgonine	Ecgonine methyl ester
Ephedrine	Epinephrine
Gentisic	Guaiaacol glycer ester
Histamine	Hydrochlorothiazide
Homatrophine	Imipramine
Ibuprofen	Isoproterenol
Ketamine	Lidocaine
Meperidine	Methadone
Methaqualone	Methylphenidate
Neomycin	Niacinamide
Perphenazine	Penicillin G
Phenylethylamine-α	Phenylpropanolamine
Promethazine	Pseudoephedrine
Quinine antidine	Salicylic acid
Tetracycline Tetrahydrozoline	Theophylline
Thioridazine	Trifluoperazine
Tryptophan	Tyramine

REFERENCES

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2. Critical Issues in Urinalysis of Abused Substances: Report of the Substance Abuse Testing committee, clinical Chemistry, 34(3), 617 (1988)
3. Blum, K., Handbook of Abusable drugs, Gardener Press, Inc., New York, NY, 1st Ed., (1984).
4. Baselt RC., Disposition of Toxic Drugs and Chemicals in Man, 3rd Ed., Cgicago, IL. Year Book Medical Publishers Inc., 780-783, (1990).
5. Mandatory Guidelines for Federal Workplace drug Testing Programs, Fed. Reg.53 (69):11970-89 (1988)
6. Stewart DJ et al: Cocaine and nor cocaine hydrolysis by liver and serum esterase. Clin Pharmacol there 1978 25:464-468.

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Interference testing

The following substances did not interfere with DOA Panel test.

Glucose	2000 mg/dl
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl
Urea	4000 mg/dl
Uric acid	10 mg/dl

Specificity

The following compounds show no cross-reactivity at concentration up to 100 µg/ml unless specified.