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REF	IVD		See external label		2°C-30°C		Σ=25 or 50 tests
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OneStep Multiple Drug RapiDip™ InstaTest

(2-9 Any Combination)

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

For in vitro Diagnostic and Forensic Use

INTENDED USE

Cortez Diagnostics, Inc. DOA RapiDip™ is an immunochromatography based one step in vitro test. It is designed for qualitative determination of drug substances in human urine specimens. This assay has not been evaluated in the point of care location and is for use by Healthcare Professionals only. Below is a list of cut-off concentrations for each drug using our test.

Amphetamine	1000 ng/ml of d-amphetamine
Barbiturate	300 ng/ml of secobarbital
Benzodiazepine	300 ng/ml of oxazepam
Cocaine	300 ng/ml of benzoylecgonine
Methodone	300 ng/ml of methadone
Methamphetamine	1000 ng/ml of (+)methamphetamine
Opiate*	300 ng/ml of morphine
Opiate II*	2000 ng/ml of morphine
Phencyclidine	25 ng/ml of phencyclidine
Cannabinoid (THC)	50 ng/ml of 11-nor- Δ^9 -THC-9-COOH

This assay provides only a preliminary analytical test result. 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 Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

* SAMHSA recommends a cut-off concentration of 2000 ng/ml for Opiates Test

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 induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effects 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.

THC. The agents of Marijuana that cause various biological effects in humans are called cannabinoid. 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 are found within hours of exposure and remain detectable in the urine for 3-10 days after smoking.

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 unmetabolized and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after opiates dose.

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 response 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.

Methadone is a synthetic opioid, clinically available. It is used clinically for the treatment of severe pain and in maintenance programs for morphine and heroin addicts. Methadone acts on the central nervous and cardiovascular systems to produce respiratory and circulatory depression. Methadone also produces miosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions. Acute higher doses induce analgesia, sedation, respiratory depression and coma. After methadone administration, the major urinary excretion products are methadone and its metabolites, EDDP and EMDP. Large individual variations in the urine excretion of methadone are output of methadone from 5-22%. Typically, following a 5 mg oral dose, methadone and EDDP account for 5% of the dose in the 24-hour urine. In those individuals on maintenance therapy, methadone may account for 5 to 50% of the dose in the 24-hour urine and EDDP may account for 3 to 25% of the dose.

Phencyclidine, commonly known as PCP, is a hallucinogen which interacts with dopamine, cholinergic and adrenergic systems. It has dose 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. The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

PRINCIPLE

Each component strip of DOA Panel 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 RapiDip device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
 - Test zone: contains drug bovine protein antigen conjugates
 - Control zone: contains Goat anti-mouse IgG antibody
 - Conjugate pad: contains mice monoclonal anti-drug antibody.
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 stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

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. Humidity sensitive product, 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. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8 °C or frozen up to 7 days. 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. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

The Cortez Diagnostics, Inc. Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from sealed foil pouch.
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.
1. Read the results at 5 minutes after adding the sample.

Do not interpret the result after 5 minutes.

INTERPRETATION OF RESULTS

Negative:

Two colored bands form on any strip of the card. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug in the specimen, it only indicates the level of tested drug in the specimen is less than cut-off level.

Positive:

One colored band form on any strip of the card. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug(s) in the specimen is above the cut-off level.

Invalid:

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

Note: A borderline(+/-) in test line zone should be considered negative result.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED RESULTS

The DOA RapiDip is a qualitative assay. It identifies the drug(s) in human urine at its cut-off concentration or higher. The concentration of the drug(s) can not 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**A. Accuracy**

The accuracy of the DOA test panels were evaluated in each component strip and in comparison to GC/MS method at the following concentration: d-amphetamine 1000ng/ml (AMP), secobarbital 300 ng/ml (BAR), oxazepam, 300 ng/ml (BZO), benzoylcegonine 300ng/ml (COC), methadone 300 ng/ml (MTD), (+)methamphetamine 1000 ng/ml (MET), phencyclidine 25 ng/ml (PCP), morphine 300 ng/ml (OPI), morphine 2000 ng/ml (OPI II) and 11-nor- Δ^9 -THC-9-COOH 50ng/ml (THC). The result of each component strip are listed below:

1. The accuracy of the amphetamine test was evaluated in comparison to GC/MS method at a cut-off of 1000 ng/ml. One hundred urine specimens with GC/MS confirmed d-amphetamine concentration were evaluated in this study. The results are summarized and presented below:

AMP Test	(-)		(+) GC/MS Positive (greater than +25%)		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%		
Positive	1	4	5	33	88.4
Negative	47	6	2	2	93.0
Total	48	10	7	35	

Positive % agreement: 88.4, Negative % agreement: 93.0

Nine specimens were found discrepant between the new screening method and the GC/MS method. When compared those data, 78% (7 out of 9) of the discrepancy specimens were found between +25% to -25% of cutoff concentration (750-1250 ng/ml).

2. The accuracy of the Cortez Diagnostics, Inc.BAR test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of secobarbital. One hundred and nineteen urine specimens with GC/MS confirmed barbiturate concentration were evaluated in this study. The results are summarized and presented below:

BAR Test	(-)		(+) GC/MS Positive (greater than +25%)		Percent agreement with GC/MS %
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%		
Positive	0	0	8	36	93.6
Negative	59	13	3	0	100.0
Total	59	13	11	36	

Positive % agreement: 93.6, Negative % agreement: 100.

Three specimens were found discrepant between the Cortez Diagnostics, Inc.BAR and GC/MS method. When compared those data, 100% (3 out of 3) of the discrepancy specimens were found between cut-off and +25% cut-off concentration (300 - 375 ng/ml).

3. The accuracy of the benzodiazepine test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of oxazepam. One hundred and fourteen urine specimens with GC/MS confirmed oxazepam concentration were evaluated in this study. The results are summarized and presented below:

BZD Test	(-)		(+)		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	6	3	6	44	84.7
Negative	39	5	1	0	97.8
Total	45	8	7	44	

Positive % agreement: 84.7, Negative % agreement: 97.8

Ten specimens were found discrepant between the Cortez Diagnostics, Inc.BZD and GC/MS method. When compared those data, 40% (4 out of 10) of the discrepancy specimens were found between -25% and +25% cut-off concentration (225 – 375 ng/ml).

4. The accuracy of the cocaine test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of benzoylecgonine. One hundred and two urine specimens with GC/MS confirmed benzoylecgonine concentration were evaluated in this study. The results are summarized and presented below:

COC Test	(-)		(+)		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	0	2	3	45	96.0
Negative	46	5	0	1	98.1
Total	46	7	3	46	

Positive % agreement: 96.0, Negative % agreement: 98.1

three specimens were found discrepant between the Cortez Diagnostics, Inc.COC and GC/MS method. When compared those data, 100% (3 out of 3) of the discrepancy specimens were found between -25% and +25% cut-off concentration (225 – 375 ng/ml).

5. The accuracy of the Cortez Diagnostics, Inc.MTD test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of methadone. One hundred and nineteen urine specimens with confirmed methadone concentrations were evaluated in this study. The results are summarized and presented below:

MTD Test	(-)		(+)		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	0	1	10	49	98.3
Negative	50	8	1	0	98.3
Total	50	9	11	49	

Positive % agreement: 98.3, Negative % agreement: 98.3.

Two specimens were found discrepant between the Cortez Diagnostics, Inc.MTD and GC/MS method. When compared those data, 100% (2 out of 2) of the discrepancy specimens were found between -25% and +25% cut-off concentration (225 – 375 ng/ml).

6. The accuracy of the methamphetamine test was evaluated in comparison to GC/MS at a cut-off of 1000 ng/ml of (+)methamphetamine. Ninety nine urine specimens with GC/MS confirmed (+)methamphetamine concentration were evaluated in this study. The results are summarized and presented below:

MET Test	(-)		(+)		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	0	0	4	41	100.0
Negative	44	6	4	0	92.6
Total	44	6	8	41	

Positive % agreement: 100, Negative % agreement: 92.6

Four specimens were found discrepant between the Cortez Diagnostics, Inc.MET and GC/MS method. When compared those data, 100% (4 out of 4) of the discrepancy specimens were found between –25% and +25% cut-off concentration (750 – 1250 ng/ml).

7. The accuracy of the opiates test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of morphine. One hundred and twenty three urine specimens with GC/MS confirmed morphine and codeine concentrations were evaluated in this study. The results are summarized and presented below:

OPI Test	(-)		(+))		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between –25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	0	2	5	70	97.4
Negative	35	7	1	3	91.3
Total	35	9	6	73	

Positive % agreement: 97.4, Negative % agreement: 91.3

Three specimens were found discrepant between the Cortez Diagnostics, Inc.OPI and GC/MS method. When compared those data, 100% (3 out of 3) of the discrepancy specimens were found between –25% and +25% cut-off concentration (225 – 375 ng/ml).

8. The accuracy of Cortez Diagnostics, Inc. Opiates II Test Strip was evaluated in comparison to GC/MS at a cut-off of 2,000ng/ml of morphine. 108 urine specimens with confirmed morphine and codeine concentrations were evaluated in this study. Among them, there are 72 real samples and 36 diluted from these samples. The results are summarized and presented below:

Opiates Test Strip	(-)		(+))		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between –25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	0	0	10	40	94.3
Negative	45	10	3	0	100.0
Total	45	10	13	40	

Positive % agreement: 94.3, Negative % agreement: 100.0.

Three specimens were found discrepant between Cortez Diagnostics, Inc. Opiates Test Strip and GC/MS method. When compared those data, 100% (3 out of 3) of the discrepancy specimens were found between –25% and +25% cut-off concentration (1500 – 2500ng/ml).

9. The accuracy of the PCP test was evaluated in comparison to GC/MS at a cut-off of 25 ng/ml of phencyclidine. Ninety nine urine specimens with GC/MS confirmed phencyclidine concentration were evaluated in this study. The results are summarized and presented below:

PCP Test	(-)		(+))		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between –25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	1	0	5	36	97.6
Negative	45	6	2	4	89.5
Total	46	6	7	40	

Positive % agreement: 97.6, Negative % agreement: 89.5

Seven specimens were found discrepant between the Cortez Diagnostics, Inc.PCP and GC/MS method. When compared those data, 28.6% (2 out of 7) of the discrepancy specimens were found between –25% and +25% cut-off concentration (18.8 – 31.3 ng/ml).

10. The accuracy of the Cortez Diagnostics, Inc.THC test was evaluated in comparison to GC/MS at a cut-off of 50 ng/ml of 11-nor- Δ^9 -THC-9-COOH. One hundred and fourteen urine specimens with GC/MS confirmed 11-nor- Δ^9 -THC-9-COOH concentration were evaluated in this study. The results are summarized and presented below:

THC Test	(-)		(+)		Percent agreement with GC/MS
	Negative By GC/MS	Near cutoff negative (between -25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	
Positive	4	3	7	30	84.1
Negative	50	5	1	0	98.2
Total	54	8	8	30	

Positive % agreement: 84.1, Negative % agreement: 98.2

Eight specimens were found discrepant between the Cortez Diagnostics, Inc. THC and GC/MS method. When compared those data, 50% (4 out of 8) of the discrepancy specimens were found between -25% and +25% cut-off concentration (37.5 – 62.5 ng/ml).

B. Sensitivity

The cut-off concentrations (sensitivity level) of DOA RapiDip has been determined to be: AMP 1000 ng/ml, BAR, 300 ng/ml, BZO 300 ng/ml, COC 300 ng/ml, THC 50 ng/ml, OPI 300 ng/ml, OPI II 2000 ng/ml, MTD 300 ng/ml, MET 1000 ng/ml and PCP 25 ng/ml.

C. Precision

The precision of DOA RapiDip was determined by conducting the test with spiked controls and interpreted the results by three individuals to verify the random error of visual interpretation. The results of 50% above and 50% below cut-off specimens are 100% agreed by three observers:

Tested Drug	Concentration (ng/ml)	Number tested	Corrected result	% Corrected result
AMP	500	40	40	100
	1500	40	40	100
BAR	150	40	40	100
	450	40	40	100
BZO	150	40	40	100
	450	40	40	100
COC	150	40	40	100
	450	40	40	100
THC	25	40	40	100
	75	40	40	100
OPI	150	40	40	100
	450	40	40	100
OPI II	1000	40	40	100
	3000	40	40	100
MTD	150	40	40	100
	450	40	40	100
MET	500	40	40	100
	1000	40	40	100
PCP	12.5	40	40	100
	37.5	40	40	100

D. Specificity

The specificity for DOA RapiDip was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The DOA RapiDip performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed did not interfere with DOA RapiDips at the listed concentrations.

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

2. Specificity

The following table lists compounds that are detected by DOA RapiDip which produced positive results when tested at levels equal or greater than the concentrations listed below:

Test	Compounds	Cut-off (ng/ml)
Amphetamine	D-Amphetamine	1,000
	D/L-Amphetamine	2,000
	(±)3,4Methylenedioxyamphetamine	2,500
	l-Amphetamine	30,000
	(+)methamphetamine	> 100 µg/ml
	(±)3,4Methylenedioxymethamphetamine	> 100 µg/ml
Barbiturate	Alphenal	100
	Barbital	150
	Pentobarbital	150
	Phenobarbital	150
	Amobarbital	300
	Secobarbital	300
	Butalbital	5,000
Benzodiazepines	Nitrazepam	100
	Chlor diazepoxide HCl	300
	Clobazam	300
	Desmethyldiazepam	300
	Oxazepam	300
	Temazepam	300
	Alprazolam	1000
	Bromazepam	1000
	Diazepam	1000
	Flunitrazepam	1000
	Lorazepam	1000
	Clonazepam	2000
	Flurazepam	100
Cocaine	Benzoylcegonine	300
	Cocaine	30,000
THC	11-nor- Δ^9 -THC-9-COOH	50
	11-nor- Δ^8 -THC-9-COOH	37.5
	11-hydroxy- Δ^9 -THC	5000
	Δ^8 -Tetrahydrocannabinol	15000
	Δ^9 -Tetrahydrocannabinol	25000
Opiate	Morphine	300
	Morphine-3- β -glucuronide	300
	Codeine	300
	Ethylmorphine	300
	Hydromrphone	300
	Nalorphine	750
	Heroin	1250
	Hydrocodone	1250
	Normorphine	2000
	Norcodeine	2500
	Naloxone	25,000
	Natrexone	100,000
	Oxycodone	> 100 µg/ml
Opiate II	Ethylmorphine	1,000
	Morphine	2,000
	Morphine-3- β -glucuronide	2,000
	Codeine	2,000
	6-Acetylmorphine	2,000
	Dihydrocodone	2,000
	Heroin	5,000
	Hydrocodone	7,500
	Hydromrphone	7,500
	Nalorphine	15,000
	Normorphine	20,000
	Norcodeine	100,000
	Naloxone	100,000
Oxycodone	100,000	
Methadone	Methadone	300
	Methadol	300
Methamphetamine	(+)Methamphetamine	1000
	(±)3,4Methylenedioxymethamphetamine	1000
	d-Amphetamine	> 100 µg/ml
	l-Amphetamine	> 100 µg/ml
	(±)3,4Methylenedioxyamphetamine	> 100 µg/ml
	Chloroquine	> 100 µg/ml
	(-)Ephedrine	> 100 µg/ml
	β -Phenylethylamine	> 100 µg/ml
	Procaine	> 100 µg/ml
	d-Pseudoephedrine	> 100 µg/ml
	Randitidinr	> 100 µg/ml
Phencyclidine	PCP	25

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

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

REFERENCES

1. Urine Testing for Drugs of Abuse, NIDA Research Monograph 73, (1986).
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., Chicago, 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 norcocaine hydrolysis by liver and serum esterase. Clin Pharmacol ther 1978 25:464-468.



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