ProScreen Drugs of Abuse Cup

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

The ProScreen Drugs of Abuse Cup is a one-step immunoassay for the qualitative detection of multiple drugs and drug metabolites in human urine at the following cutoff concentrations:

Test	Calibrator	Cut-off (ng/ml)
AMP	d-Amphetamine	1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC150	Benzoylecgonine	150
COC300	Benzoylecgonine	300
MDMA	3,4-methylenedioxymethamphetamine	500
MET500	d-Methamphetamine	500
MET1000	d-Methamphetamine	1000
MTD	Methadone	300
OPI300	Morphine	300
OPI2000	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ^9-THC-9-COOH	50

The configurations of the ProScreen Drugs of Abuse Cup consist of any combination of the drugs listed above with or without specimen validity test. The specimen validity test provides information regarding the integrity of urine sample in the drugs of abuse test through the semi-quantitative determination of creatinine, nitrite, pH, bleach/oxidant, and specific gravity in human urine. The ProScreen Drugs of Abuse Cup is used to obtain a visual, qualitative result and is intended for professional use only.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION

Amphetamine/Methamphetamine, amphetamine, and metabolites are potent central nervous system stimulants. Acute higher doses induce euphoria, alertness, and sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, methamphetamine is also excreted to some extent unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Barbiturates are classified as central nervous system depressants. These compounds produce a state of intoxication that is similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and impaired judgment. Depending on the dose, frequency, and duration of use, one can rapidly develop tolerance, physical dependence and psychological dependence on barbiturates. Barbiturates are taken orally, or by intravenous and intramuscular injections. They are excreted in urine as parent compound as well as metabolites.

Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Parent compounds, as well as metabolites are excreted in the urine.

Buprenorphine is a synthetic thebaine derivative that has both analgesic and opioid antagonist properties. As an analgesic, it is about 25 to 40 times more potent than morphine. Symptoms of overdosage include confusion, dizziness, pinpoint pupils, hallucinations, hypotension, respiratory difficulty, seizures and coma. Burpenorphine is metabolized in man primarily by N-dealkylation and conjugation to form norbuprenorphine, which is pharmacologically active, and conjugates of buprenorphine and norbuprenorphine. Within 144 hours of a single intramuscular dose of drug, 95% is eliminated, with 68% in the feces and 27% in the urine. Buprenorphine and its metablites in urine may be detected as a result of buprenorphine, norbuprenorphine, Buprenorphine-3-beta-D-glucuronide, and Norbuprenorphine-3-beta-D-glucuronide.

Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour), and can be generally detected for 24 to 60 hours after cocaine use or exposure.

3,4-methylenedioxymethamphetamine (MDMA) is classified as both a stimulant and a hallucinogen. Like methamphetamine, adverse effects of MDMA/Ecstasy use include jaw clenching, teeth grinding, dilated pupils, perspiring, anxiety, blurred vision, vomiting, and increased blood pressure and heart rate. Overdose of 3,4-methylenedioxymethamphetamine may cause heart failure or extreme heart stroke. 3,4-methylenedioxymethamphetamine is taken orally in tablets or capsules and excreted in urine as parent compound as well as metabolites.

Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver and has a biological half-life of 15-60 hours.

Opiates, such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. Heroin is quickly metabolized to morphine, morphine glucuronide and 6-acetylmorphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the urine indicates heroin, morphine, and/or codeine use.

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. It produces potent euphoria, analgesic and sedative effects, and has a dependence liability similar to morphine. Oxycodone is most often administered orally and is metabolized by demethylation to noroxycodone and oxymorphone followed by glucuronidation and excreted in urine. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

Phencyclidine, commonly known as “angel dust” and “crystal cyclone", is an arylcyclohexylamine that is originally used as an anesthetic agent and a veterinary tranquilizer. The drug is abused by oral or nasal ingestion, smoking, or intravenous injection. It produces hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It is well absorbed following all routes of administration. Unchanged PCP is excreted in urine in moderate amounts (10% of the dose).

Propoxyphene is a mildly effective narcotic analgesic that has been in clinical use. It is less potent than codeine, and bears a close structural relationship to methadone. Propoxyphene is available in oral formulations either as the hydrochloride (32 or 65 mg) or as the napsylate salt (50 or 100 mg), and is often found in combination with aspirin or acetaminophen. Overdosage with propoxyphene can result in stupor, coma, convulsions, respiratory depression, cardiac arrhythmias, hypotension, pulmonary edema and circulatory collapse. Propoxyphene is metabolized primarily via N-demethylation to norpropoxyphene. The amounts of metabolites excreted in the 20 hour urine following a 130 mg single oral dose of propoxyphene hydrochloride were: 1.1% propoxyphene, 13.2% norpropoxyphene and 0.7% dinorpropoxyphene.

Tetrahydrocannabinol is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit 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. When marijuana is ingested, the drug is metabolized by the liver, the primary metabolite of marijuana excreted in the urine is 11-nor- Δ -9-tetrahydrocannabinol-9-carboxylic acid. Therefore, the presence of detected cannabinoids including the primary carboxyl metabolite in the urine indicates marijuana/cannabis use.

Tricyclic antidepressants (TCAs) have been prescribed for depression and compulsive disorders. Because of the possibility of causing serious cardiac complications, TCAs can be lethal if misused at high doses. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The length of time following drug use of 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.

Adulteration of urine samples may cause erroneous results in drugs of abuse test by either interfering with the drug screening test and/or destroying the drugs in the urine. Dilution of urine with water is probably the simplest urine adulteration method. Bleach, vinegar, Visine, sodium bicarbonate, sodium nitrite, Drano, soft drinks and hydrogen peroxide are the examples of compounds used to adulterate the urine sample. It is important to insure the integrity of urine samples in drugs of abuse test.

TEST PRINCIPLE

The ProScreen Drugs of Abuse Cup is based on the principle of competitive immunochemical reaction between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample for the limited antibody binding sites. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate (or antibody) in the test region and a pad containing colored antibody (or drug-protein)-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and dehydrate the antibody (or drug-protein)-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein (or antibody) band on the test region. When drug is absent in the urine, the colored antibody (or drug-protein)-colloidal gold conjugate and immobilized drug-protein (or antibody) bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein.

with drug-protein for the limited antibody sites. The line on the test region will become less intense with increasing drug concentration. When a sufficient concentration of drug is present in the urine, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (or drug-protein)-colloidal gold conjugate to the drug-protein (or antibody) on the test region. Therefore, the presence of the line on the test region indicates a **negative** result for the drug and the absence of the test line on the test region indicates a **positive** result for the drug.

A visible line generated by a different antigen/antibody reaction is also present at the control region of the test strip. This line should always appear, regardless of the presence of drugs or metabolites in the urine sample. This means that a **negative** urine sample will produce both test line and control line, and a **positive** urine sample will generate only control line. The presence of control line serves as a built-in control, which demonstrates that the test is performed properly.

The ProScreen Drugs of Abuse Cup for the specimen validity test is based on the color response of chemical indicators at presence of adulterants. Creatinine (Cr), nitrite (Ni), pH, bleach/oxidant (Bl), and specific gravity (S.G.) are tested to determine the integrity of urine samples.

Cr: Creatinine reacts with a creatinine indicator in an alkaline medium to forms a purplish-brown color complex. The color intensity is directly proportional to the concentration of creatinine. Urine samples with creatinine concentrations of less than 20 mg/ml are dilute, which may be indicative of adulteration.

Ni: Nitrite reacts with the reagent's aromatic amine to form a diazonium salt which couples with an indicator to yield a pink-red/purple color complex. Urine samples containing nitrite at levels greater than 15 mg/dl are considered adulterated.

pH: The pH determination of urine sample is based on color change of indicator in different acidic or basic medium. The normal urine pH ranges from 4 to 9. Urine pH below 4 or above 9 indicates adulteration of the specimen with acids or alkalines.

Bl: Bleach or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, brown, or orange color indicates adulteration with bleach or other oxidizing agents.

S.G.: The S.G. test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors changes from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration. Urine specific gravity below 1.005 or above 1.025 is considered abnormal, which may indicate adulteration.

REAGENTS & MATERIALS SUPPLIED

- 25 individually wrapped test devices. Each device consists of different test strips in a plastic test strip holder. The test strip contains a colloidal gold pad coated with antibody (or drug-protein) and rabbit antibody. It also contains a membrane coated with drug-bovine protein conjugate (or antibody) in the test band and goat anti-rabbit antibody in the control band adulterant pads when applicable.
- One instruction sheet
- Specimen collection container
- One Adulteration Color Comparison Chart for interpretation of adulteration test result (when applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- External positive and negative controls

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.
- Test device should remain sealed until ready for use.
- Do not use the test kit after the expiration date.
- A positive test result does not always mean an individual has taken the drug illegally as the drug can be administered legally. Do not store and or expose reagent kits at temperature greater than 30°C. Do not freeze.

STORAGE

The ProScreen Drugs of Abuse Cup should be stored at 2-30°C (36-86°F) in the original sealed pouch. Do not freeze. Do not store and or expose reagent kits at temperature greater than 30°C (86°F).

SPECIMEN COLLECTION AND HANDLING

Fresh urine does not require any special handling or pretreatment. A fresh urine sample should be collected in the container provided. Alternately, a clean, dry plastic or glass container may be used for specimen collection. If the specimen will not be tested after the specimen collection, the specimen may be refrigerated at 2-8°C up to 2 days or frozen at -20°C for longer period of time. Specimens that have been refrigerated must be equilibrated to room temperature prior to testing. Specimens previously frozen must be thawed and mixed thoroughly prior to testing.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory attire.

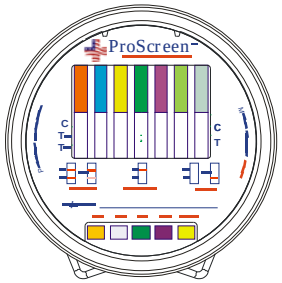
ASSAY PROCEDURE

Preparation

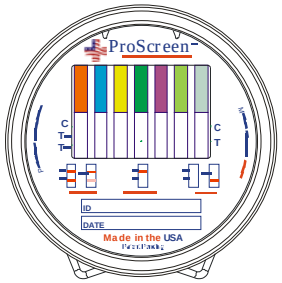
1. If specimen, control, or test devices have been stored at refrigerated temperatures, allow them to warm to room temperature before testing.
2. Do not open test device pouch until ready to perform the test.

Testing

1. Remove lid test device from the sealed pouch.
2. Secure test device to the filled specimen cup, then place the cup on its side, as shown in the illustration below, to activate testing.
3. Read the results of adulteration test by visually comparing the color of reagent pads to the corresponding blocks on the Color Chart at the time indicated.
4. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes.



Drugs of Abuse Cup with specimen validity test



Drugs of Abuse Cup without specimen validity test

INTERPRETATION OF RESULTS

Specimen Validity Tests:

Specimen validity test results are obtained by directly comparing the color of each test pad with the color block of Adulteration Color Comparison Chart. Potentially adulterated urine sample will produce abnormal color response. Unadulterated urine sample will produce normal color response.

Drugs of Abuse Tests:

Negative (-): Colored lines appear in both Control Region (C) and Test Region (1, 2, or T). The line in the control region is the control line, which is used to indicate proper performance of the device. The line in the test region is the drug probe line. The test line may have varying intensity either weaker or stronger in color than that of the control line. A negative result for a drug indicates that the concentration of that drug in urine is below the cutoff level.

Positive (+): Colored line appears in the control region. **No line appears in the test region.** The complete absence of a test line indicates a positive result for that drug. A preliminary positive result for a drug indicates that the concentration of that drug in urine is at or above the cutoff level.

Invalid: No colored line appears in the control region. If the control line does not form, the test result is inconclusive and should be repeated.

NEGATIVE (-) | POSITIVE (+) | INVALID

QUALITY CONTROL

An internal procedural control is included in the test device. A line must form in the Control band region regardless of the presence or absence of drugs or metabolites. The presence of the line in the Control region indicates that the proper sample volume has been used and that the reagents are migrating properly. If the line in the Control region does not form, the test is considered invalid.

To ensure proper kit performance, it is recommended that the test devices be tested once a week with external controls. External controls are available from commercial sources. It is important to make sure that the control values are within established limits. If the values of external control do not fall within established limits, the test results are invalid. Additional controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

LIMITATIONS 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 as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
- If adulteration is suspected, the test should be repeated with new sample.

PERFORMANCE CHARACTERISTICS

Accuracy

The accuracy of the ProScreen Drugs of Abuse Cup was evaluated in comparison to commercially available drug screen tests. Sixty (60) negative urine samples collected from presumed non-user volunteers were tested by both ProScreen Drugs of Abuse Cup and commercially available drug screen tests. Of these negative urine samples tested, all were found negatives by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (TCA concentrations were determined by HPLC), were tested by ProScreen Drugs of Abuse Cup and commercial drug screen tests. The results of accuracy study are presented below:

Drug Test		GC/MS (<-50% C/O)	GC/MS (–50% C/O to C/O)	GC/MS (C/O to +50% C/O)	GC/MS (>+50% C/O)	% Agreement with GC/MS
AMP	(+)	0	0	10	55	98.5
	(-)	15	9	1	0	100
BAR	(+)	0	1	5	83	97.8
	(-)	15	7	2	0	95.7
BUP	(+)	0	0	8	35	97.7
	(-)	18	6	1	0	100
BZO	(+)	0	2	13	37	100
	(-)	18	18	0	0	94.7
COC150	(+)	0	1	7	60	100
	(-)	15	10	0	0	96.2
COC300	(+)	0	0	8	71	98.8
	(-)	15	8	1	0	100
MDMA	(+)	0	1	6	37	100
	(-)	24	6	0	0	96.8
MET500	(+)	0	2	8	64	100
	(-)	15	4	0	0	90.5
MET1000	(+)	0	0	5	58	98.4
	(-)	20	8	1	0	100
MTD	(+)	0	0	6	65	98.6
	(-)	15	5	1	0	100
OPI300	(+)	0	1	6	77	100
	(-)	16	6	0	0	95.7
OPI2000	(+)	0	2	9	45	100
	(-)	15	6	0	0	91.3
OXY	(+)	0	1	6	47	100
	(-)	15	7	0	0	95.7
PCP	(+)	0	0	4	56	96.8
	(-)	15	4	2	0	100
PPX	(+)	0	0	6	64	98.6
	(-)	10	7	1	0	100
TCA	(+)	0	1	12	9	100
	(-)	23	11	0	0	97.1
THC	(+)	0	1	24	32	100
	(-)	15	12	0	0	96.4

Precision

The precision of the ProScreen Drugs of Abuse Cup was evaluated by testing three lots of the test devices at four study sites with spiked drug sample solutions on three consecutive days. Sample concentrations were confirmed by GC/MS.

AMP (ng/ml)	0	500	750	1000	1250	1500
(+/-)	0/135	0/135	34/101	75/60	110/25	135/0
BAR (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	34/101	74/61	102/33	135/0
BUP (ng/ml)	0	5	7.5	10	12.5	15
(+/-)	0/135	0/135	33/102	73/61	101/34	135/0
BZO (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	29/106	75/60	107/28	135/0
COC 150(ng/ml)	0	75	112.5	150	187.5	225
(+/-)	0/135	0/135	33/102	75/60	105/30	135/0
COC300 (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	30/105	65/70	96/36	135/0
MDMA (ng/ml)	0	250	375	500	625	750
(+/-)	0/135	0/135	35/100	75/60	95/40	135/0
MET500 (ng/ml)	0	250	375	500	625	750
(+/-)	0/135	0/135	32/103	77/58	99/36	135/0
MET1000 (ng/ml)	0	500	750	1000	1250	1500
(+/-)	0/135	0/135	31/104	77/58	98/37	135/0
MTD (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	31/104	69/66	95/40	135/0
OPI300 (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	33/102	70/65	95/40	135/0
OPI2000 (ng/ml)	0	1000	1500	2000	2500	3000
(+/-)	0/135	0/135	37/98	76/59	104/31	135/0
OXY (ng/ml)	0	50	75	100	125	150
(+/-)	0/135	0/135	50/85	86/49	111/24	135/0
PCP (ng/ml)	0	12.5	18.75	25	31.25	37.5
(+/-)	0/135	0/135	26/109	62/73	99/36	135/0
PPX (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	34/101	77/58	103/32	135/0
TCA (ng/ml)	0	500	750	1000	1250	1500
(+/-)	0/135	0/135	24/111	60/75	99/36	135/0
THC (ng/ml)	0	25	37.5	50	62.5	75
(+/-)	0/135	0/135	27/108	58/77	91/44	135/0

Specificity

The specificity for the ProScreen Drugs of Abuse Cup was determined by testing 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. The following compounds produce positive results when tested at levels greater than the concentrations listed.

Compound	Conc. (ng/ml)	Compound	Conc. (ng/ml)
Amphetamine			
d-Amphetamine	1,000	d-Methamphetamine	50,000
dl-Amphetamine	2,500	(+/-)3,4-MDMA	50,000
(+/-)3,4-MDA	1,250		
Barbiturates			
Secobarbital	300	Butabarbital	400
Allobarbital	600	Butalbital	300
Alphenal	200	Butethal	450
Amobarbital	1500	Pentobarbital	400
Aprobarbital	300	Phenobarbital	450
Barbital	1500		
Benzodiazepines			
Oxazepam	300	Flunitrazepam	300
Alprazolam	400	Flurazepam	300
Bromazepam	250	Lorazepam	500
Chlordiazepoxide	300	Medazepam	300
Clobazam	1000	Nitrazepam	250
Clonazepam	500	Nordiazepam	150
Clorazepate	150	Prazepam	500
Desalkylflurazepam	200	Temazepam	200
Diazepam	450	Triazolam	450
Estazolam	300		

Buprenorphine

Buprenorphine	10	Buprenorphine-3-beta-D-glucuronide	7.5
Norbuprenorphine	25,000		
Codeine	>100,000		
Morphine	>100,000	Norbuprenorphine-3-beta-D-glucuronide	150
Nalorphine	10,000		

Cocaine (150)

Benzoylecgonine	150	Cocaethylene	>100,000
Cocaine	5,000	Ecgonine methyl ester	>100,000
Ecgonine	>100,000		

Cocaine (300)

Benzoylecgonine	300	Cocaine	300

Methamphetamine (500)

d-Methamphetamine	500	(+/-)3,4-MDMA	2,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	100,000
(+/-)3,4-MDEA	50,000	Mephentermine	50,000
(+/-)3,4-MDA	100,000		

Methamphetamine (1000)

d-Methamphetamine	1000	(+/-)3,4-MDMA	3,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	>100,000
(+/-)3,4-MDEA	50,000	Mephentermine	75,000
(+/-)3,4-MDA	100,000		

MDMA

(+/-)3,4-MDMA	500	(+/-)3,4-MDA	4,000
(+/-)3,4-MDEA	450		

Methadone

(+/-) Methadone	300	Methadol	1,500

Opiates (300)

Morphine	300	Hydrocodone	500
Codeine	300	Hydromorphone	500
Ethylmorphine	300	Morphine-3-glucuronide	300
Heroin	750	Nalorphine	5,000

Opiates (2000)

Morphine	2,000	Hydrocodone	4,000
Codeine	2,000	Hydromorphone	5,000
Ethylmorphine	1,000	Morphine-3-glucuronide	2,500
Heroin	5,000	Nalorphine	5,000

Oxycodone

Oxycodone	100	Morphine	>100,000
Hydrocodone	5,000	Codeine	50,000
Hydromorphone	50,000	Heroin	>100,000

PCP

Phencyclidine	25	Tenocyclidine	2,000

PPX

D-Propoxyphene	300	D-Norpropoxyphene	300

THC

11-nor-Δ^9-THC-9-COOH	50	Δ^9-tetrahydrocannabinol	5,000
11-hydroxy-Δ^9-THC	1,000	Cannabinol	10,000
Δ^8-tetrahydrocannabinol	5,000	Cannabidiol	>100,000

Tricyclic Antidepressant

Nortriptyline	1,000	Promazine	1,500
Nordoxepin	2,000	Desipramine	400
Trimipramine	2,000	Doxepin	3,000
Amitriptyline	1,500	Maprotiline	2,000

Interference

Two pools of drug-free urine were spiked with drug standards to 50% below and 50% above cutoff concentrations. The drug concentrations were confirmed by GC/MS. The following compounds were evaluated for potential positive and/or negative interference with the ProScreen Drugs of Abuse Cup. All compounds were dissolved in the spiked sample solutions and tested with ProScreen Drugs of Abuse Cup. An unaltered sample was used as a control. No positive interference or negative interference was found for the following compounds when tested at concentrations up to 100 μg/ml.

Acetaminophen	Diphenhydramine	(+/-)-Norephedrine
Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic Acid	Ethanol	Phenothiazine
Aspartame	Furosemide	l-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Theophylline
Creatine	(+)-Naproxen	Tyramine
Dexbrompheniramine	Niacinamide	4-Dimethylaminoantipyrine
Dextromethorphan	Nicotine	(1R,2S)-(-)-N-Methyl-Ephedrine

Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 4-9 and tested using ProScreen Drugs of Abuse Cup. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen pH do not interfere with the performance of the test.

Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.003-1.040 and tested using ProScreen Drugs of Abuse Cup. An unaltered sample was used as a control. The results demonstrate that varying ranges of specimen specific gravity do not interfere with the performance of the test.

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