D8-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

D..Interference

The following compounds were evaluated for potential positive and/or negative interference with the DrugCheck Drug Screen Cup All compounds were dissolved in the drug control solutions with 50%

below and 50% above cutoff concentrations and tested with Biotech Screening Bio 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 mg/ml.

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

e.Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 4-9 and tested using Biotech Screening Bio 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.

f.Effect of Specimen Specific Gravity

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to specific gravity 1.003-1.04 and tested using Biotech Screening Bio 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.

ADULTERATION TESTS

Specimen validity/adulteration tests are not in vitro diagnostic assays. Therefore, information regarding these tests is not subject to FDA review.

Adulteration of urine samples may cause erroneous results in a drug 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, eye drops, sodium bicarbonate, sodium nitrite, Drano, soft drinks and hydrogen peroxide are examples of adulterants used to adulterate urine samples. It is important to insure the integrity of urine samples in drugs of abuse testing.

The DrugCheck Drug Screen Cup with adulteration test is based on the color response of chemical indicators in the presence of adulterants. Creatinine (CR), nitrite (NI), pH, bleach/oxidant (OX), specific gravity (SG), and glutaraldehyde (GL) 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. A urine sample with a creatinine concentration of less than 20 mg/dL is 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. A urine sample containing nitrite at a level greater than 15 mg/dl is considered adulterated.

pH: The pH determination of urine sample is based on color change of indicator in an acidic or basic medium. Normal urine pH ranges from 4 to 9. A urine pH below 4 or above 9 indicates adulteration with acid or base to the sample.

OX/BI: 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.

SG: The specific gravity 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. A urine specific gravity below 1.005 or above 1.025 is considered abnormal.

ASSAY PROCEDURE FOR ADULTERATION TEST

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 (Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the adulteration strips to the printed color blocks on the color chart. No instrumentation is required.

1. Remove the test cup from the sealed pouch.
2. Hand the cup to the individual being tested.
3. Collect the urine into the cup. A minimum of 30 ml is recommended.
4. Secure the test device cap to the specimen cup.
5. Authorized personnel should remove the tear-off label.
6. Read the adulteration strips within 2 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. If adulteration is indicated, we recommend not to interpret the drug test results and either retest the urine or collect another specimen.
7. Read results of the drugs of abuse tests at 5 minutes. Do not interpret results after 10 minutes.

ALCOHOL TEST

INTENDED USE

The Urine Alcohol Test Strip is intended for use as a rapid method to detect the presence of alcohol in urine for blood alcohol concentration (BAC) greater than 0.04%. It has been published that the concentration of alcohol in urine is almost equal to that in blood.[4]

The rapid test is intended for the semi-quantitation of ethyl alcohol in human urine. TO CONFIRM THE CONCENTRATION OF POSITIVE SPECIMENS, AN ALTERNATE, NON-ENZYMATIC TECHNOLOGY SUCH AS HEADSPACE GAS CHROMATOGRAPHY SHOULD BE USED.

EXPLANATION OF THE TEST

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.04% (0.04g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. [1-3]

Determination of ethyl alcohol in blood and urine is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. The Urine Alcohol Test Strip is designed as the screen tool to rapidly determine if the BAC level is higher than 0.04% by testing urine specimen.

INTERPRETATION OF RESULTS

Negative: Almost no color change by comparing with the background. The negative result indicates that the urine alcohol concentration (UAC) is less than 0.04%.
Positive: A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.04% or higher.
Invalid: The test should be considered invalid If only the edge of the reactive pad turned color that might be ascribed to insufficient sampling.
The subject should be re-tested.

LIMITATION OF PROCEDURE

The Urine Alcohol Test Strip is designed for use with human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.

There is a possibility that technical or procedural errors, as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to the Interference section for list of substances that will interfere with the test results.

Manufactured by:
Express Diagnostics Int'l, Inc.
1550 Industrial Drive
Blue Earth, MN 56013 USA

DC005 Rev A 07/2013

EC REP
CEPartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands

CE

DRUGCHECK® Drug Screen Cup

FOR IN VITRO DIAGNOSTIC USE AND POINT OF CARE TESTING

INTENDED USE

The DRUGCHECK® Drug Screen 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	5/10
BZO	Oxazepam	300
COC	Benzoylecgonine	150/300
COT	Cotinine	200
EDDP	Methadone	100
K2	JW-018; JW-073	50
KET	Ketamine	1000
MDMA	3,4-methylenedioxymethamphetamine	500
MET500	d-Methamphetamine	500/1000
MET	d-Methamphetamine	1000
MTD	dl-Methadone	300
OPI300	Morphine	300
OPI	Morphine	2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor-Δ9-THC-9-COOH	50/300
TML	Tramadol	200
ALC	Alcohol	BAC >.04

The configurations of the DRUGCHECK Drug Screen Cup consist of any combination of the drugs listed above. The DRUGCHECK Drug Screen 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) and Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmation methods.

SUMMARY AND EXPLANATION

Amphetamine/Methamphetamine and their metabolites are potent central nervous system stimulants. Acute doses induce euphoria, alertness, and sense of increased energy and power. Responses from chronic use can include anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine and amphetamine are excreted in urine as unchanged drug along with deaminated or hydroxylated derivatives. Methamphetamine also metabolize to amphetamine in the body. As a result, urine specimens from most methamphetamine users contain both unchanged parent drug and the amphetamine metabolite.

Barbiturates are classified as central nervous system depressants. These products 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, tolerance, physical dependence and psychological dependence on barbiturates can occur. Barbiturates are taken orally, or by intravenous and intramuscular injections. Members of the barbiturate drug class typically excrete in urine as parent compound and 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. Most benzodiazepines are excreted in the urine as conjugates and metabolites.

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. Buprenorphine 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 as unchanged drug and the various conjugates and metabolites, with 68% in the feces and 27% in the urine.

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.

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when 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. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.
EDDP 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primarymetabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours.

K2/Spice is a common name for synthetic marijuana which contains chemicals JW-018; JW-073 In addition, other synthetic cannabis compound metabolities can be detected, MAM2201 (100ng/ml); JWH-0398 (200ng/mL); and JWH-210 (300ng/mL).

3,4-methylenedioxymethamphetamine (MDMA) is classified as both a stimulant and a hallucinogen. Like methamphetamine, adverse effects of 3,4-methylenedioxymethamphetamine 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 heat stroke. 3,4-methylenedioxymethamphetamine is taken orally in tablets or capsules and is excreted in urine as parent compound metabolites including methylenedioxyamphetamine (MDA).

Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction and pain management. 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 6-acetylmorphine (6-AM), morphine, an morphine glucuronide. Codeine also partially metabolizes to morphine and morphine glucuronide. Thus, the presence of morphine glucuronide in the urine can indicate 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. 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 since the 1950's. It is less potent than codeine, and bears a close structural relationship to methadone. Propoxyphene is available in oral formulations either as the hydrochloride or as the napsylate salt, and is often dosed 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 (THC) 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 extensively metabolized by the liver, the primary metabolite of marijuana excreted in the urine is 11-nor-D-9-tetrahydrocannabinol-9-carboxylic acid. The elimination of THC and metabolites in urine is highly dependent on

frequency of drug use and the physiology of the user.

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. 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 urine test result may occur is dependent upon several factors, including the frequency of drug use, amount of drug, the user's metabolic rate, drug excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

TEST PRINCIPLE

The DRUGCHECK Drug Screen 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 in the test region and a pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and rehydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by the capillary action to the immobilized drug-protein band on the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region as the antibody complexes with the drug-protein.

When drug is present in the urine, it will compete 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-colloidal gold conjugate to the drug-protein 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.

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 and rabbit antibody. It also contains a membrane coated with drug- protein conjugate in the test band and goat anti-rabbit antibody in the control band. For the device with adulteration test, an adulteration test strip is also included in each device.

· One instruction sheet

· Security seals (if applicable)

· Adulteration Color Chart (when applicable)

MATERIAL REQUIRED BUT NOT PROVIDED

· Timer

· Specimen collection container

· 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 DRUGCHECK Drug Screen 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.

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 a 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 FOR DRUG TEST

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

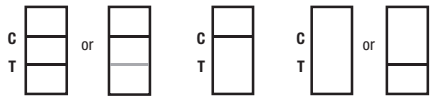
1. Remove test device from the sealed pouch and write donor name or ID on the label in the section provided.
2. Hand the cup to the individual being tested.
3. Remove lid and collect the urine into the cup. Ensure the specimen is above the minimum level. A minimum of 30 ml is recommended.
4. Secure lid to the filled specimen cup.
5. The cup must be returned immediately to the collector.
6. Authorized personnel at collection site to remove the tear-off label.
7. Read results of test in 5 minutes. Do not interpret result after 10 minutes.

INTERPRETATION OF RESULTS

Negative (-): A colored line appears at the control region (C) and a colored line appears at the test region (T). The appearance of a control line and test line indicates a negative test result for that particular test. The test lines may have varying intensity either weaker or stronger in color than that of the control line.

Positive (+): A colored line appears at the control region no colored line appears at a specific drug test region. The complete absence of a test line indicates a preliminary positive result for that particular 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 sufficient 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 and must be repeated.

To ensure proper kit performance, it is recommended that the DRUGCHECK Drug Screen Cup devices be tested using external controls with each new lot of product and each new shipment. External controls are available from commercial sources. Additional testing may be necessary to comply with the requirements accrediting organizations and/or local, state, and/or federal regulators.

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, and those that do not interfere with test performance.

· If adulteration is suspected, the test should be repeated with new sample.

PERFORMANCE CHARACTERISTICS

A.Accuracy

The accuracy of the DRUGCHECK Drug Screen Cup was evaluated in comparison to commercially available drug screen tests and GC/MS. Sixty (60) negative urine samples collected from presumed non-user volunteers were tested by both DRUGCHECK Drug Screen Cup and commercially available drug screen tests.

Of these negative urine samples tested, all were correctly identified as negative by both methods. In a separate study, positive urine samples, obtained from clinical laboratories where the drug concentrations were determined by GC/MS (HPLC for TCA), were tested by DRUGCHECK Drug Screen 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	2	6	47	100
	(-)	15	6	0	0	91.3
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

B.Precision

A study was conducted at three physician offices and the test strip manufacturer in an effort to determine the precision of the DrugCheck Drug Screen Cup across three (3) consecutive days. Testing was conducted on the Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine (300 and 150 assays), Marijuana, Methamphetamine (1000 and 500 assays), Methylenedioxymethamphetamine, Methadone, Opiates (2000 and 300 assays), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants assays using three different lots of product to demonstrate the within-run, between-run and between-operator precision. An identical panel of coded samples, containing drugs at specific concentrations around each assay cutoff was blinded and tested at each site. The correlation with expected results for the solutions targeted to +/- 50% of the cutoff was >99% across all lots, all sites and all operators.

C. Specificity

The specificity for the DrugCheck Drug Screen 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 below.

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 (5/10)			
Buprenorphine	5/10	Buprenorphine-3-beta-D-glucuronide	7.5
Norbuprenorphine	2500	Norbuprenorphine-3-beta-D-glucuronide	150
Codeine	>100,000		
Morphine	>100,000		
Nalorphine	10,000		
Cocaine Metabolite(150/300)			
Benzoylecgonine	150/300	Cocaethylene	>100,000
Cocaine	5,000	Ecgonine methyl esters	>100,000
Ecgonine	>100,000		
Methamphetamine (500/1000)			
d-Methamphetamine	500/1000	(+/-)3,4-MDMA	2,000
d-Amphetamine	50,000	l-Methamphetamine	10,000
l-Amphetamine	>100,000	Ephedrine	50,000
(+/-)3,4-MDEA	50,000	Mephentermine	50,000
(+/-)3,4-MDA	100,000		
(+/-)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	250	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 (diacetylmorphine)	5,000	Nalorphine	5,000
Oxycodone			
Oxycodone	100	Morphine	>100,000
Hydrocodone	5000	Codeine	50,000
Hydromorphone	50,000	Nalorphine	5,000
PCP			
Phencyclidine	25	Tenocyclidine	2,000
PPX			
d-Propoxyphine	300	d-Norpropoxyphene	300
THC			
11-nor-D9-THC-9-COOH	50	D9-tetrahydrocannabinol	5,000
11-hydroxy-D9-THC	1,000	Cannabinol	10,000