

DRUGCHECK® Drug Screen Cup II

FOR FORENSIC USE ONLY

INTENDED USE

The DRUGCHECK® Drug Screen Cup II 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)
MET500	Methamphetamine	500
BUP	Buprenorphine	10
COC150	Benzoylcegonine	150
PPX	Propoxyphene	300

The configurations of the DRUGCHECK® Drug Screen Cup II consist of any combination of the drugs listed above. The DRUGCHECK® Drug Screen Cup II 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

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.

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 overdose 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, with 68% in the feces and 27% in the urine. Buprenorphine and its metabolites 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 benzoylcegonine in a short period of time. Benzoylcegonine 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.

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. Overdose 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.

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 adulterants used to adulterate the urine sample. It is important to insure the integrity of urine samples in drugs of abuse test.

TEST PRINCIPLE

The DRUGCHECK® Drug Screen Cup II 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-bovine protein conjugate in the test band and goat anti-rabbit antibody in the control band adulterant pads when applicable.
- * One instruction sheet

MATERIAL REQUIRED BUT NOT PROVIDED

- * Timer
- * Specimen collection container
- * External positive and negative controls

WARNINGS AND PRECAUTIONS

- * For professional forensic 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 II 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 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.

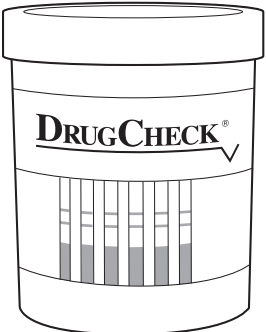
ASSAY PROCEDURE

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 the test cup from the sealed pouch.
- 2. Issue the cup to the individual to be tested.
- 3. Collect the urine into the cup. Ensure the specimen is above the minimum level.
- 4. The cup must be returned immediately to the collector. Authorized personnel should remove the tear-off label.
- 5. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes.



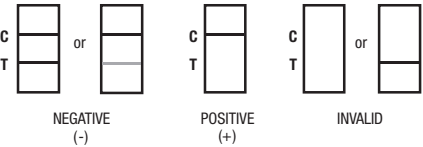
DrugCheck® Drug Screen Cup

INTERPRETATION OF RESULTS

Negative (-): Two colored lines should be observed in the viewing window. The line in the test region is the drug probe line. The line in the control region is the control line, which is used to indicate proper performance of the device. The test line may have varying intensity either weaker or stronger in color than that of the control line.

Positive (+): Only one colored line appears in the control region. The complete absence of a test line with a clear white background indicates a positive result.

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.



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 DRUGCHECK® Drug Screen Cup II 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 DRUGCHECK® Drug Screen Cup II 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, were tested by DRUGCHECK® Drug Screen Cup II 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)	% Agree- ment with GC/ MS
MET500	(+)	0	2	8	64	100
	(-)	15	4	0	0	90.5
BUP	(+)	0	0	8	35	97.7
	(-)	18	6	1	0	100
COC150	(+)	0	1	7	60	100
	(-)	15	10	0	0	96.2
PPX	(+)	0	0	6	64	98.6
	(-)	10	7	1	0	100

Precision

The precision of the DRUGCHECK® Drug Screen Cup II 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.

MET500 (ng/ml)	0	250	375	500	625	750
(+/-)	0/135	0/135	32/103	77/58	99/36	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
COC 150 (ng/ml)	0	75	112.5	150	187.5	225
(+/-)	0/135	0/135	33/102	75/60	105/30	135/0
PPX (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	34/101	77/58	103/32	135/0

Specificity

The specificity for the DRUGCHECK® Drug Screen Cup II 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)
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		
Buprenorphine			
Buprenorphine	10	Buprenorphine-3-beta-D-glucuronide	7.5
Norbuprenorphine	25,000	Norbuprenorphine-3-beta-D-glucuronide	150
Codeine	>100,000		
Nalorphine	10,000		
Cocaine (150)			
Benzoylcegonine	150	Cocaethylene	>100,000
Cocaine	5,000	Ecgonine methyl esters	>100,000
Ecgonine	>100,000		
PPX			
D-Propoxyphine	300	D-Norpropoxyphene	300

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 DRUGCHECK® Drug Screen Cup II. All compounds were dissolved in the spiked sample solutions and tested with DRUGCHECK® Drug Screen Cup II. 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	Ibuprofen
Acetone	(+/-)-Isoproterenol
Albumin	Ketamine
Ampicillin	Levorphanol
Ascorbic Acid	Lidocaine
Aspartame	(+)-Naproxen
Aspirin	Niacinamide
Atropine	Nicotine
Benzocaine	(+/-)-Norephedrine
Bilirubin	Oxalic Acid
Caffeine	Penicillin-G
Chloroquine	Pheniramine
(+)-Chlorpheniramine	Phenothiazine
(+/-)-Chlorpheniramine	l-Phenylephrine
Creatine	β-Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethorphan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride
Erythromycin	Sulindac
Ethanol	Theophylline
Furosemide	Tyramine
Guaiacal Glyceryl Ether	4-Dimethylaminoantipyrine
Hemoglobin	(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 DRUGCHECK® Drug Screen Cup II. 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 1.003-1.04 and tested using DRUGCHECK® Drug Screen Cup II. 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.

BIBLIOGRAPHY OF SUGGESTED READING

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