DrugCheck® Drug of Abuse Tests

Package Insert for Single Test Strip, Multi-Drug Screening Dipcard and Multi-Drug Screen Test Cup.

This Instruction Sheet is for testing of any combination of Amphet-amine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine (Opiates), Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

A rapid, DRUGCHECK® screening test for the simultaneous, qualitative detection of multiple drugs and drug Metabolites in human urine.
For Professional and In Vitro Diagnostic Use Only.

INTENDED USE

The DRUGCHECK® Drug of Abuse Test is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZD)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine(MET)	D-Methamphetamine	1,000 ng/mL
Methylenedioxymetham-phetamine (MDMA)	D,L Methylenedioxy-methamphetamine	500 ng/mL
Opiates (OPI 300)	Morphine	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

Configurations of the DRUGCHECK® Drug of Abuse Test can consist of any combination of the above listed drug analytes. This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.1 Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The DRUGCHECK® Drug of Abuse Test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine. The DRUGCHECK® Drug of Abuse Test is a rapid urine screening test that utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine without the use of an instrument.

AMPHETAMINE (AMP) Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The DRUGCHECK® Drug of Abuse Test yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). 2

BARBITURATES (BAR) Barbiturates produce a wide spectrum of central nervous system depression, from mild sedation to coma, and have been used as sedatives, hypnotics, anesthetics, and anticonvulsants. Barbiturates are classified as ultrashort, short, intermediate, and long-acting. These drugs are primarily used for insomnia and preoperative sedation daytime sedation and the treatment of seizure disorders. Veterinarians use pentobarbital, a long-acting barbiturate, for anesthesia and euthanasia.

Barbiturates are common drugs of abuse taken orally or intravenously. They produce symptoms similar to intoxication. Chronic use will develop tolerance, physical dependence and psychological dependence on barbiturates. Overdoses can cause profound shock, coma, or death.

Shorter acting barbiturates (Allobarbital, Alphenal, Amobarbital, Aprobarbital, Butabarbital, Butalbital, Butethal, Pentobarbital, Secobarbital) can be detected for only 1 to 4 days, while long-acting barbiturates (Barbital, Phenobarbital) can be detected for 2 to 3 weeks. Normally the suggested detection period for the Barbiturates in urine is 4 to 7 days.

The DRUGCHECK® Drug of Abuse Test yields a positive result when the Barbiturates (Secobarbital) in urine exceed 300 ng/mL.

BENZODIAZEPINES (BZD) Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

The DRUGCHECK® Drug of Abuse Test yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL.

COCAINE (COC) Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine.2.4 Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.4

The DRUGCHECK® Drug of Abuse Test yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). 2

MARIJUANA (THC) THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

The DRUGCHECK® Drug of Abuse Test yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). 2

METHADONE (MTD) Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.13

The DRUGCHECK® Drug of Abuse Test yields a positive result when the Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINE (MET) Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The DRUGCHECK® Drug of Abuse Test yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA) MDMA, ECSTASY; 3,4-METHYLENEDIOXY-N-METHYLAMPHETAMINE was first identified by a DEA Lab in 1972. MDMA is a Schedule 1 synthetic, psychoactive drug possessing stimulant and hallucinogenic properties. MDMA possesses chemical variations of the stimulant amphetamine or methamphetamine and a hallucinogen, most often mescaline.

Ecstasy is said to produce empathy, decreased anxiety, relaxation and heightened senses. MDMA also suppresses appetite, thirst and the need to sleep. Because of this in combination with dancing and increased activity can cause severe dehydration and exhaustion. Adverse effects may include nausea, cold sweats, chills, hallucinations, increased body temperature, tremors, teeth clenching, tremors, double vision and muscle cramps. Long term after-effects of MDMA include anxiety, paranoia and depression. This is most likely attributed to the decreased serotonin levels found in the brain for up to three weeks after their last dose. The National Institute of Mental Health conducted a study in 1998 to support this. It was found that the use of MDMA severely damaged the neurons in the brain that transmit serotonin. Serotonin is the chemical that is used in learning, sleep, and integration of emotion. The study concluded that even recreational users of the drug might be at risk of developing permanent damage that can manifest depression, anxiety, memory loss, and neuropsychotic disorders.

In addition to these troubling facts, recent research is pointing to the real cause of the long term effects of MDMA. The drug acts primarily on the serotonin receptor sites in the brain, enabling them to take in large quantities of serotonin. It also enables them to take in other chemicals in the brain. Namely, it takes in dopamine and as the serotonin receptor sites attempt to break the dopamine down, it produces hydrogen peroxide. Which many researches believe is the cause of long term damage to serotonin receptors.

The DRUGCHECK® Drug of Abuse Test yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPIATES (OPI 300) Opiates refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

The DRUGCHECK® Drug of Abuse Test yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATES (2000) Opiates refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.4

The DRUGCHECK® Drug of Abuse Test yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

OXYCODONE (OXY) Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names as OxyContin® (controlled release), OxyIR®, OxyFast®(immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

The DRUGCHECK® Drug of Abuse Test yields a positive result when the Oxycodone in urine exceeds 100 ng/mL.

PHENCYCLIDINE (PCP) Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intranasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.5 Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).6

The DRUGCHECK® Drug of Abuse Test yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PROPOXYPHENE (PPX) Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The DRUGCHECK® Drug of Abuse Test yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL.

TRICYCLIC ANTIDEPRESSANTS (TCA) TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. 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 DRUGCHECK® Drug of Abuse Test yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE

The DRUGCHECK® Drug of Abuse Test is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates, Propoxyphene, Oxycodone or Tricyclic Antidepressants.

PRECAUTIONS

- For Professional Use Only. · For In Vitro Diagnostic Use Only.
- Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood8,9, the use of gloves is recommended to avoid

unnecessary contact with the specimen.
· The used test card and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be allowed to settle to obtain a clear specimen for testing.

Specimen Storage Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

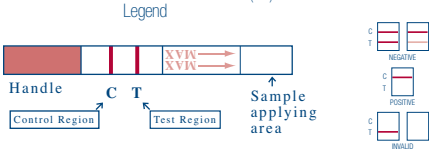
Materials Provided · Test devices · Desiccant · Package insert / Instructions · Color Procedure Card (for tests with Adulterations strips)

Materials Required But Not Provided · Specimen collection container · Disposable gloves · Timing device (i.e. timer, clock, watch, etc.)

DIRECTIONS FOR USE

[For Single Test Strip]
1) Remove the test strip from the foil pouch. Label the test strip with patient or control identifiers.
2) Immerse the test strip into the urine with the arrow end pointing toward the urine. **DO NOT IMMERSE THE TEST STRIP BEYOND THE MAX FILL LINE, AS INDICATED BY ARROWS.** Remove the test strip at or after 15 seconds and lay the test strip flatly on a non-absorbant clean surface.
3) Read results at five (5) minutes.
DO NOT INTERPRET RESULT AFTER TEN (10) MINUTES.

Legend



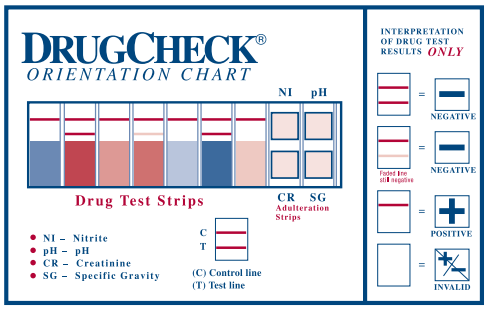
[For Multi-Test Dipcard]
1) Remove the test device from the protective foil pouch.
2) Remove the cap from the test device. Label the device with patient or control identifications.
3) Immerse the absorbent tip into the urine sample for fifteen (15) seconds. **URINE SAMPLE SHOULD NOT TOUCH THE PLASTIC DEVICE.**
4) Replace the cap over the absorbent tip and lay the device flatly on a non-absorbent clean surface.
5) Read results at five (5) minutes.
DO NOT INTERPRET RESULT AFTER TEN (10) MINUTES.

[For Integrated Test Cup]
1) Remove the test cup from the protective foil pouch.
2) Issue the device to the individual to be tested.
3) Have the donor void directly into the test cup. Ensure the specimen is above the minimum fill line on the test cup label.
The cup must be returned immediately to the collector. Authorized personnel at the collection site should remove the tear-off label and read the results at five (5) minutes post collection. DO NOT INTERPRET RESULT AFTER TEN (10) MINUTES.
4) If adulteration test strips are included in the test, remove the tear off label and read the adulteration test results (1) minute post collection by comparing the adulteration test strips to the color chart included. Do not interpret results after (2) minutes. Abnormal colors may indicate the specimen has been adulterated.

INTERPRETATION OF RESULTS

NEGATIVE: Two lines appear. * One line visible in the control region (C), and another apparent line adjacent visible in the test region (T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative if a line is visible. There is no meaning attributed to the line color intensity or width.
POSITIVE: One line appears in the control region (C). No line whatsoever appears in the test region (T). The lack of a line in the test region (T) indicates a preliminary positive result for the corresponding drug of that specific test region. Send this urine specimen to a certified laboratory for a more specific confirmation by GC/MS.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, contact your supplier for technical support.

Adulteration Test Strips: Adulteration results are obtained by direct comparison of the reacted strips with the color blocks on the enclosed cards. Adulterated urine will show result colors under the "Abnormal" block colors of the color chart enclosed. Unadulterated samples will show strip colors similar to the "Normal" block colors of the colors chart enclosed.
pH: Normal pH ranges from 4.5 to 8.0 Values below pH 4.0 or above pH 9.0 are indicative of adulteration.
Specific gravity: Random urine may vary in specific gravity from 1.003 – 1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016 – 1.022. Elevated urine specific gravity values may be obtained in the presence of moderate quantities of protein. A urine specimen with a specific gravity level of less that 1.003 can be an indication of substitution. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is substituted.
Creatinine: Daily creatinine excretion, related to muscle mass of the human body, is usually constant. A urine specimen with creatinine levels of less than 5 mg/dl is an indication of substitution. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution, samples with creatnine level of lower than 20mg/dl should be considered diluted.
Nitrite: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In the test cup with adulteration nitrite levels above 15 mg/dl are considered abnormal.



QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The DRUGCHECK® Drug of Abuse Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. 3,4,7
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy A side-by-side comparison was conducted using The DRUGCHECK® Drug of Abuse Test and other commercially available rapid drug tests. Testing was performed on 120 specimens per drug type previously collected from subjects presenting for drug screen testing. All the presumptive positive and negative results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZD	Oxazepam, Nordiazepam, _ -OH-Alprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-_ ^{9}-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
MET	Methamphetamine
MDMA	D,L Methylenedioxymethamphetamine, Methylenedioxyamphetamine
OPI, OPI 300	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BZD
Positive Agreement	98%	100%	100%
Negative Agreement	100%	100%	98%
Total Results	99%	100%	99%

	COC	THC	MTD
Positive Agreement	98%	98%	100%
Negative Agreement	100%	100%	100%
Total Results	99%	99%	100%

	MET	MDMA	OPI 300
Positive Agreement	98%	100%	98%
Negative Agreement	100%	100%	100%
Total Results	99%	100%	99%

%Agreement with Commercial Kit

	OPI	OXY	PCP
Positive Agreement	98%	100%	98%
Negative Agreement	100%	100%	100%
Total Results	99%	100%	99%

%Agreement with Commercial Kit

	PPX	TCA
Positive Agreement	98%	98.5%
Negative Agreement	100%	100%
Total Results	99%	99%

%Agreement with GC/MS

	AMP	BAR	BZD
Positive Agreement	95%	98.5%	95.7%
Negative Agreement	100%	98%	98%
Total Results	97.5%	98.2%	96.8%

	COC	THC	MTD
Positive Agreement	95%	95%	98.5%
Negative Agreement	100%	100%	96%
Total Results	97.5%	97.5%	97%

	MET	MDMA	OPI 300
Positive Agreement	95%	97.1%	95%
Negative Agreement	100%	98%	100%
Total Results	97.5%	97.5%	97.5%

	OPI	PCP	TCA
Positive Agreement	95%	95%	95.7%
Negative Agreement	100%	100%	98%
Total Results	97.5%	97.5%	96.8%

Forty (40) clinical samples for each drug were run using each strip contained within The DrugCheck® Drug of Abuse Test by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the untrained operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel. *Note: TCA was based on HPLC data.

	AMP	BAR	BZD
Positive Agreement	95%	97.4%	95.7%
Negative Agreement	100%	97.6%	100%
Total Results	97.5%	97.5%	97.5%

	COC	THC	MTD
Positive Agreement	96%	96%	93.7%
Negative Agreement	100%	100%	97.9%
Total Results	98%	98%	96.2%

	MET	MDMA	OPI 300
Positive Agreement	96%	92.5%	96%
Negative Agreement	100%	100%	100%
Total Results	98%	96.2%	98%

	OPI	OXY	PCP
Positive Agreement	100%	95%	95%
Negative Agreement	96%	100%	100%
Total Results	98%	97.5%	97.5%

	PPX	TCA
Positive Agreement	95%	97.5%
Negative Agreement	100%	100%
Total Results	97.5%	98.7%

Reproducibility

Reproducibility studies were carried out using commercially available standards. Each standard was diluted in normal, drug-free urine to give the appropriate concentration. Each specimen, at each concentration of analyte, was tested four times daily, in duplicate, for five consecutive days. A total of 40 determinations were made at each concentration. The results are given below:

AMPHETAMINE (AMP)

Amphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

BARBITURATES (BAR)

Secobarbital Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

BENZODIAZEPINES (BZD)

Oxazepam Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

COCAINE (COC)

Amphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

MARIJUANA (THC)

11-nor-Δ^9-THC-9 COOH Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
25	40	40 negative	>99%
37.5	40	40 negative	>99%
50	40	40 positive	>99%
75	40	40 positive	>99%

METHADONE (MTD)

Benzoylecgonine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

METHAMPHETAMINE (MET)

Methamphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxy-methamphetamine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
250	40	40 negative	>99%
375	40	40 negative	>99%
500	40	40 positive	>99%
750	40	40 positive	>99%

OPIATES 300 (OPI 300)

Morphine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

OPIATES (OPI 2000)

Morphine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
1,000	40	40 negative	>99%
1,500	40	40 negative	>99%
2,000	40	40 positive	>99%
3,000	40	40 positive	>99%

OXYCODONE (OXY)

Oxycodone Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
50	40	40 negative	>99%
75	40	40 negative	>99%
100	40	40 positive	>99%
150	40	40 positive	>99%

PHENCYCLIDINE (PCP)

Phencyclidine Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
12,5	40	40 negative	>99%
19	40	40 negative	>99%
25	40	40 positive	>99%
37.5	40	40 positive	>99%

PROPOXYPHENE (PPX)

Propoxyphene Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
150	40	40 negative	>99%
225	40	40 negative	>99%
300	40	40 positive	>99%
450	40	40 positive	>99%

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortiptyline Conc. (ng/mL)	Total number of Determinations	Result	Precision
No drug present	40	40 negative	>99%
500	40	40 negative	>99%
750	40	40 negative	>99%
1,000	40	40 positive	>99%
1,500	40	40 positive	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		BAR	
		-	+	-	+
0% Cut-off	10	10	0	10	0
-50% Cut-off	10	10	0	10	0
-25% Cut-off	10	10	0	10	0
Cut-off	10	0	10	0	10
+25% Cut-off	10	0	10	0	10
+50% Cut-off	10	0	10	0	10

Drug concentration Cut-off Range	n	BZD		COC	
		-	+	-	+
0% Cut-off	10	10	0	10	0
-50% Cut-off	10	10	0	10	0
-25% Cut-off	10	10	0	10	0
Cut-off	10	0	10	0	10
+25% Cut-off	10	0	10	0	10
+50% Cut-off	10	0	10	0	10

Drug concentration Cut-off Range	n	THC		MTD		MET		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	OPI 300		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+
0% Cut-off	10	10	0	10	0	10	0	10	0
-50% Cut-off	10	10	0	10	0	10	0	10	0
-25% Cut-off	10	10	0	10	0	10	0	10	0
Cut-off	10	0	10	0	10	0	10	0	10
+25% Cut-off	10	0	10	0	10	0	10	0	10
+50% Cut-off	10	0	10	0	10	0	10	0	10

Drug concentration Cut-off Range	n	PPX		TCA	
		-	-	-	+
0% Cut-off	10	10	10	10	0
-50% Cut-off	10	10	10	10	0
-25% Cut-off	10	10	10	10	0
Cut-off	10	0	0	0	10
+25% Cut-off	10	0	0	0	10
+50% Cut-off	10	0	0	0	10

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.03) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The DRUGCHECK® Drug of Abuse Test was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the DRUGCHECK® Drug of Abuse Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Methadone, Methylenedioxymeth amphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with The DRUGCHECK® Drug of Abuse Test at concentrations of 100 ng/mL.

Non Cross-Reacting Compounds

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
L-Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine*
Bilirubin
D/L-Brompheniramine
Caffeine
Cannabidiol
Chloralhydrate
Chloramphenicol
Chlorothiazide
D/L-Chloropheniramine
Chlorpromazine
Chloroquine
Cholesterol
Clonidine
Cortisone
L-Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Ecgonine methyl ester
L -_ -Ephedrine
b-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
[1R,2S] (-) Ephedrine
L(–)-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
O-Hydroxyhippuric acid
p-Hydroxyamphetamine
p-Hydroxytyramine
Ibuprofen
Iproniazid
D/L-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Meperidine
Meprobamate
Methoxyphenamine
Methylphenidate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norethindrone
D-Norpropoxyphene
Noscapine
D/L-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine hydrochloride
Perphenazine
Phenelzine
Trans-2-phenylcyclo-propylamine hydrochloride
L-Phenylephrine
_-Phenylethylamine
Phenylpropanolamine
Prednisolone
Prednisone
D/L-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinine
Quindine
Ranitidine
Salicylic acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone
3-acetate
Tetrahydrocortisone 3 (b-D-glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
D/L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Tryptamine
D/L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by DRUGCHECK® Drug of Abuse Test at a read time of 5 minutes.

Drug	Concentration (ng/ml)
Amphetamine (AMP)	
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)- Methylenedioxyamphetamine (MDA)	1,500
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	15
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZD)	
Oxazepam	300
Alprazolam	196
_-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Chlordiazepoxide HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE (COC)	
Benzoylecogonine	300
Cocaethylene	300
Cocaine	300

MARIJUANA (THC)	
11-Hydroxy-D9-Tetrahydrocannabinol	5,000
11-Nor-D8-Tetrahydrocannabinol	50
11-Nor-D9-Tetrahydrocannabinol	50
11-Nor-D9-Tetrahydrocannabinol-9 Carboxylic Glucuronide	2,500
D8-Tetrahydrocannabinol	20,000
D9 –Tetrahydrocannabinol	20,000
METHADONE (MTD)	
Methadone	300
Doxylamine	50,000
Methamphetamine (MET)	
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/-methamphetamine	1,000
+methamphetamine	Ranitidine (Zantac)
1,000	500,000
(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	2,500
MDA	100,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxymethamphetamine HCll (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
OPIATES (OPI 300)	
6-acetylmorphine	500
Codeine	300
Ethylmorphine	15,00
Heroin	300
Hydromorphone	2,000
Hydrocodone	1,250
Meperidine	300,000
Morphine	300
Morphine-3-glucuronide	300
Oxycodone	negative at 100,000

OPIATES (OPI 2000)	
Codeine	2,000
Hydromorphone	5,000
Oxycodone	negative at 100,000
Morphine Sulfate	2,000
Morphine-3-b-D-glucuronide	2,000
Morphine-6-b-D-glucuronide	2,000
Methadone	negative at 100,000
Nalorphine	negative at 100,000
Heroin	2,000
Ethylmorphine	5,000
Meperidine	5,000,000
Oxycodone (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethylmorphine	25,000
Hydrocodone	1,580
Hydromorphone	12,500
Oxymorphone	1,580
Thebaine	50,000
Phencyclidine (PCP)	
Phencyclidine	25
Phencyclidine-d5	10000
Propoxyphene (PPX)	
D-Propoxyphene	300
D-Norpropoxyphene	300
Tricyclic Antidepressants (TCA)	
Notriptyline	1,000
Nordoxepine	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

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