

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® Dip Drug Test. All compounds were dissolved in the spiked sample solutions and tested with the DrugCheck® Dip Drug Test. 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	Dopamine	Pheniramine
Acetone	(+/-)-Epinephrine	Phenothiazine
Albumin	Erythromycin	l-Phenylephrine
Ampicillin	Ethanol	*-Phenylethylamine
Ascorbic Acid	Furosemide	Procaine
Aspartame	Glucose	Quinidine
Aspirin	Guaiacol Glyceryl Ether	Ranitidine
Atropine	Hemoglobin	Riboflavin
Benzocaine	Ibuprofen	Sodium Chloride
Bilirubin	(+/-)-Isoproterenol	Sulindac
Caffeine	Ketamine	Theophylline
Chloroquine	Levorphanol	Tyramine
(+)-Chlorpheniramine	Lidocaine	4-Dimethylaminoan-tipyrine
(+/-)-Chlorpheniramine	(+)-Naproxen	(1R,2S)-(-)-N-Methyl-Ephedrine
Creatine	Niacinamide	
Dextrompheniramine	Nicotine	
Dextromethorphan	(+/-)-Norephedrine	
	Oxalic Acid	
Diphenhydramine	Penicillin-G	

Effect of Specimen pH

Drug sample solutions with 50% below and 50% above cutoff concentrations were adjusted to pH 4-9 and tested using the DrugCheck® Dip Drug Test. 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 the DrugCheck® Dip Drug Test. 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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DRUGCHECK® Dip Drug Test

FOR IN VITRO DIAGNOSTIC USE

INTENDED USE

The DrugCheck® Dip Drug Test 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	1,000
BAR	Secobarbital	300
BZO	Oxazepam	300
COC300	Benzoylcegonine	300
MDMA	3,4-methylenedioxymethamphetamine	500
MET1000	d-Methamphetamine	1,000
MTD	Methadone	300
OPI2000	Morphine	2,000
OXY	Oxycodone	100
PCP	Phencyclidine	25
TCA	Nortriptyline	1,000
THC	11-nor- Δ^9 -THC-9-COOH	50

The configurations of the DrugCheck® Dip Drug Test can consist of any combination of the drugs listed above. The DrugCheck® Dip Drug Test 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.

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.

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 may 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 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).

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.

TEST PRINCIPLE

The DrugCheck® Dip Drug Test 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 rehydrates 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 cup
- * 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® Dip Drug Test 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.

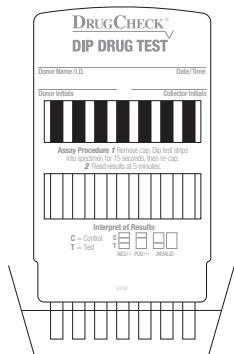
ASSAY PROCEDURE

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

3. Remove test card from the sealed pouch and remove the cap from the sampling tips.
4. Immerse the sampling tips into the urine specimen for about 15 seconds and then place the test on a flat surface with the cap on.
5. Read results of drugs of abuse tests in 5 minutes. Do not interpret result after 10 minutes.

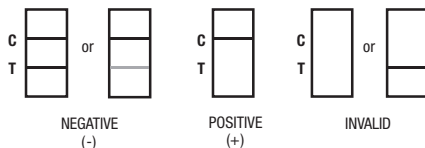


INTERPRETATION OF RESULTS

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. A negative result for a drug indicates that the concentration of that drug in urine is below the cutoff level.

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. This is only a preliminary positive result. Sample should be confirmed with a more specific method before a positive conclusion is made. 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.



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® Dip Drug Test 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® Dip Drug Test 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 DrugCheck® Dip Drug Test 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
BZO	(+)	0	2	13	37	100
	(-)	18	18	0	0	94.7

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
COC300	(+)	0	0	8	71	98.8
	(-)	15	8	1	0	100
MDMA	(+)	0	1	6	37	100
	(-)	24	6	0	0	96.8
MET1000	(+)	0	0	5	58	98.4
	(-)	20	8	1	0	100
MTD	(+)	0	0	6	65	98.6
	(-)	15	5	1	0	100
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
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 DrugCheck® Dip Drug Test 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
BZO (ng/ml)	0	150	225	300	375	450
(+/-)	0/135	0/135	29/106	75/60	107/28	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
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
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
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 of the DrugCheck® Dip Drug Test 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	Butobarbital	400
Allobarbitol	600	Butalbital	300
Alphenal	200	Butethal	450
Amobarbital	1500	Pentobarbital	400
Aprobarbital	300	Lorazepam	>100,000
Barbital	1500	Phenobarbital	450
Benzodiazepines			
Oxazepam	300	Flunitrazepam	300
Alprazolam	400	Flurazepam	300
Bromazepam	250	Lorazepam	500
Chlordiazepoxide	300	Medazepam	300
Clobazam	1,000	Nitrazepam	250
Clonazepam	500	Nordiazepam	150
Clorazepate	150	Prazepam	500
Desalkylflurazepam	200	Temazepam	200
Diazepam	450	Triazolam	450
Estazolam	300		
Cocaine (300)			
Benzoylcegonine	300	Cocaine	300
Methamphetamine (1000)			
d-Methamphetamine	1,000	(+/-)-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
Doxylamine	>100,000		
Opiates (2000)			
Morphine	2,000	Hydrocodone	4,000
Codeine	2,000	Hydromorphone	50,000
Ethylmorphine	5,000	6-Monoacetylmorphine	3,000
Heroin	5,000	Morphine-3-glucuronide	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
THC			
11-nor- Δ^8 -THC-9-COOH	50	Δ^8 -tetrahydrocannabinol	5,000
11-hydroxy- Δ^8 -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
Amtriptyline	1,500	Maprotiline	2,000