DrugCheck® Waive™ Dip Tests

One step, rapid screening tests for the qualitative detection of drug(s) and drug metabolite(s) in human urine.
For forensic use only.
For in vitro diagnostic use only.

INTENDED USE

Drug Screening Test is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drug(s) and drug metabolite(s) in human urine at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
AMP/Amphetamine	**D-Amphetamine**	1000 ng/mL
BAR/Barbiturates	**Secobarbital**	300 ng/mL
BZO/Benzodiazepines	**Oxazepam**	300 ng/mL
COC/Cocaine	**Benzoylecgonine**	300 ng/mL
THC/Marijuana	**Delta-9-THC-COOH**	50 ng/mL
MTD/Methadone	**Methadone**	300 ng/mL
mAMP/Methamphetamine	**D-Methamphetamine**	1000 ng/mL
MDMA/Methylenedioxymethamphetamine	**MDMA**	500 ng/mL
MOP/Opiates 300	**Morphine**	300 ng/mL
OPI/Opiates 2000	**Morphine**	2000 ng/mL
OXY/Oxycodone	**Oxycodone**	100 ng/mL
PCP/Phencyclidine	**Phencyclidine**	25 ng/mL
TCA/Tricyclic Antidepressants	**Nortriptyline**	1000 ng/mL
-	-	-

Drug Screening Test provides only a preliminary analytical test result. The test is not intended to be used in monitoring the drug levels. A more specific alternate method must be used in order to confirm the test result. Gas Chromatography/ Mass Spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

Drug Screening Test is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in urine.

AMPHETAMINE / AMP

Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and overall feeling of well-being. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Large doses and extended usage can result in higher tolerance levels and physiological dependency leading to substance abuse. The effect 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. **Drug Screening Tests** yield a positive result when Amphetamines in urine exceed 1000 ng/mL, which is the suggested screening cut-off for positive specimens by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

BARBITURATES / BAR

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) t long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse. **Drug Screening Tests** yield a positive result when secobarbital in urine exceed 300ng/mL.

BENZODIAZEPINES / BZO

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse. **Drug Screening Tests** yield a positive result when oxazepam in urine exceed 300ng/mL.

COCAINE/ COC

Cocaine is an alkaloid present in Coca leaves (Erythyroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In large dose, Cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Cocaine is excreted in the urine primarily as Benzoylecgonine, which can generally be detected for 24 – 48 hours after cocaine exposure. **Drug Screening Tests** yield a positive result when the Cocaine metabolite in urine exceeds 300ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration(SAMHSA, USA).

MARIJUANA / THC

THC (Δ^9 – tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). THC is central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short-term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increases heart rate. Large doses of marijuana could develop tolerances and physiological dependency and lead its abuse. The main metabolite excreted in the urine is 11-nor- Δ^9 – tetrahydrocannabinol-9-carboxylic acid (Δ^9 –THC-COOH), which is found in the urine within hours of exposure and remain detectable for 3-10 days after smoking. **Drug Screening Tests** yield a positive result when the concentration of THC-COOH in urine exceeds 50ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA,USA).

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). It is administered either orally, or by intravenous or intra-muscular injection. The duration of effect of methadone is 12 – 24 hours. Its major urinary excretion products are methadone, EDDP (2- ethylidene-1,5-dimethyl-3,3-diphenylprryolidine), and EMDP (2- ethyl-5-methy-3,3-diphenylpyrrolidine). **Drug Screening Tests** yield a positive result when the concentration of Methadone in urine exceeds 300ng/mL.

METHAMPHETAMINES / mAMP

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 can be taken orally, injected, or inhale. 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. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10 to 20 % of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. **Drug Screening Tests** yield a positive result when the concentration of Methamphetamine in urine exceeds 1000ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE /MDMA

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2 – 3 hours. **Drug Screening Tests** yield a positive result when the concentration of MDMA in urine exceeds 500ng/mL.

OPIATES 300/MOP

Opiates refer 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. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake. **Drug Screening Tests** yield a positive result when the concentration of Opiates in urine exceeds 300ng/mL.

OPIATES 2000/OPI

Opiates refer 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. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake. **Drug Screening Tests** yield a positive result when the concentration of Opiates in urine exceeds 2000ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

OXYCODONE / OXY

Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, Oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of Oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy. **Drug Screening Tests** yield a positive result when the concentration of Oxycodone in urine exceeds 100ng/mL.

PHENCYCLIDINE / PCP

Phencyclidine, commonly known as PCP or "angel dust" is used primarily as recreational drug due to its hallucinogenic effects. It is generally self administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects of PCP are very much dose related. Small amounts of

Phencyclidines (PCP) are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heat rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of Phencyclidine (PCP) can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%). **Drug Screening Tests** yield a positive result when the concentration of Phencyclidine in urine exceeds 25ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA,USA).

TRICYCLIC ANTIDEPRESSANTS/TCA

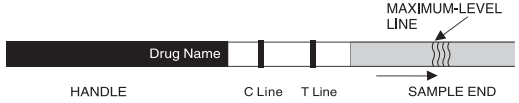
Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been used for screening the abuse of TCAs. **Drug Screening Test** yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

PRINCIPLE OF TEST

Drug Screening Test is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of urine specimen is applied to the sample pad of the test device, the urine specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

A NEGATIVE specimen produces two distinct red colored bands in both T line and C line.
A POSITIVE specimen produces only one distinct red colored band in the C line.

REAGENTS



Drug Screening tests contain membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against to Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Marijuana, Phencyclidine, and Tricyclic Antidepressants.

MATERIALS PROVIDED

1.Test strip/device/card.
2.Product insert.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers
3. External controls

PRECAUTIONS

1. For *forensic* use only.
2. For *in vitro diagnostic use* only.
3. Do not use after the expiration date.
4. The test kits should remain in the sealed pouch until use.
5. All specimens should be considered potentially hazardous and handle in the same way as an infectious material.
6. All used tests should be discarded according to federal, state and local regulation.

STORAGE AND STABILITY

Store test kits in the sealed pouch at 2° to 30°C. The test kits are stable through the expiration date printed on the sealed pouch. The test kits must remain in the sealed pouch until use. If store at 2° to 8°C, allow the test kits to reach room temperature (15° to 30°C) before performing the test. Dot not freeze, do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

Fresh urine specimens should be collected directly into a clean and dry container. Urine collected at any time of the day may be used for testing. Urine specimen exhibiting visible precipitates should be centrifuged, filtered or allowed the precipitates to settle to obtain a clear specimen for testing.

For best results, test a fresh specimen immediately following collection. Storage of specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8 ℃) prior to using.

TEST PROCEDURE

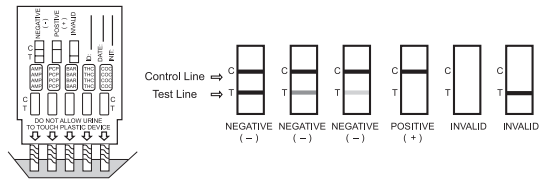
1. Equilibrate the test device, or the test strip, urine specimens or external controls to room temperature (15-30℃) prior to testing.
2. Removing the test device from the sealed pouch and dip the device into the specimen for at least 15 to 20 seconds or until migration occurs. Immerse the strip(s) of the test devices just below the top line of the wave line on the test strips, do not dip the devices above the top line.
3. Place the test device or the test strip on a flat dry surface.
4. Read the test result at 5 minutes.

INTERPRETATION OF RESULTS

Positive: One colored line appears in the Control zone (C). No line appears in the Test Zone (T). The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug level is above the detectable level.
Note: The samples with positive results should be confirmed with more specific method.

Negative*: One colored line appears in the Control zone, and **another colored line appears in the Test zone**. The negative result indicates the drug or its metabolite level is below the detectable level.
**Note:The shade of the colored line(s) in the Test Zone (T) may vary. The result should be considered negative whenever there is even a faint line.*

Invalid: No line appears in the Control zone. If no C line or no C line and T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new test device. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new test strip or device. If the problem persists, discontinue using the current lot and contact your suppliers.



QUALITY CONTROL

1. Built-in Control: the test contains a built-in control feature, the C line. The presence of the C line indicates that the test is performed properly. If a C line does not form, the test is considered invalid. In this case, the testing should be repeated with a new device.
2. External Quality Control: Control materials are not supplied with this kit. However, it is recommended that positive and negative controls should be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.
3. Test each new lot and shipment by using external quality control materials (positive and negative), with each new untrained operator, monthly for storage, and as otherwise required by your lab internal quality system procedures.

LIMITATIONS

1. **Drug Screening Test** provides only a qualitative, preliminary testing result. A more specific testing method must be used in order to obtain a confirmed testing result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.
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 or other oxidizing agents may produce erroneous results. If suspected, the test should be repeated with a fresh specimen and a new device.
4. The urine specimens with bacterial contamination should not be used for testing, as these contaminations may interfere with the test and cause false results.
5. A positive result does not indicate the level of intoxication, the route of the drug administration or the concentration of the drug in the urine.
6. 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 test.
7. Test does not distinguish between drugs of abuse and certain medications.
8. Certain foods or food supplements may cause a false positive result.

PERFORMANCE CHARACTERISTICS

Accuracy:

The comparison studies were conducted using **Drug Screening Tests** and commercially available rapid drugs of abuse tests. The studies were performed on approximately 128 clinical specimens per drug type previous collected from the clinical settings. Presumptive positive results were confirmed by GC/MS. The following results are summarized from these comparison studies:

% Agreement with Commercial Kit

	AMP	BAR	BZO	COC	THC	MTD	mAMP	MDMA	MOP	OPI	OXY	PCP	TCA	
Positive Agreement	100%	98%	97%	100%	100%	98%	100%	97%	100%	100%	98%	100%	100%	
Negative Agreement	98%	98%	97%	100%	98%	97%	98%	97%	100%	100%	98%	98%	98%	
Total Agreement	99%	98%	97%	100%	99%	97.5%	99%	97%	100%	100%	98%	99%	99%	

% Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD	mAMP	MDMA	MOP	OPI	OXY	PCP	TCA*	
Positive Agreement	100%	98%	97%	100%	100%	98%	100%	97%	100%	100%	98%	100%	100%	
Negative Agreement	98%	98%	97%	100%	98%	97%	98%	97%	100%	100%	98%	98%	98%	
Total Agreement	99%	98%	97%	100%	99%	97.5%	99%	97%	100%	100%	98%	99%	98%	

TCA* : TCA was based on HPLC data.

Sensitivity:

Sensitivity of **Drug Screening Tests** was characterized by validating the test performance around the claimed cut-off concentration of each test. The cut-off of each test was determined by the lowest concentration of drug which produces at least 50% positive testing results in total numbers of determinations. The results were summarized as the following:

Amphetamine Sensitivity Study:

Amphetamine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
500	20	20/0	0%
750	20	20/0	0%
1250	20	1/19	95%
1500	20	0/20	100%

Barbiturates Sensitivity Study:

Barbiturates Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

Benzodiazepines Sensitivity Study:

Benzodiazepines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

Cocaine Sensitivity Study:

Cocaine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	7/13	65%
450	20	0/20	100%

Methamphetamines Sensitivity Study:

Methamphetamines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
500	20	20/0	0%
750	20	20/0	0%
1250	20	0/20	100%
1500	20	0/20	100%

MDMA Sensitivity Study:

MDMA Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
250	20	20/0	0%
375	20	20/0	0%
625	20	0/20	100%
750	20	0/20	100%

Opiates 300 Sensitivity Study:

Opiates 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	0/20	100%
450	20	0/20	100%

Opiates 2000 Sensitivity Study:

Opiates 2000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
1000	20	20/0	0%
1500	20	13/7	35%
2500	20	0/20	100%
3000	20	0/20	100%

Methadone Sensitivity Study:

Methadone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
150	20	20/0	0%
225	20	20/0	0%
375	20	1/19	95%
450	20	0/20	100%

Oxycodone Sensitivity Study:

Oxycodone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
50	20	20/0	0%
75	20	20/0	0%
125	20	3/17	85%
150	20	0/20	100%

Phencyclidine Sensitivity Study:

Phencyclidine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
12.5	20	20/0	0%
18.75	20	20/0	0%
31.25	20	5/15	75%
37.5	20	0/20	100%

Marijuana Sensitivity Study:

Marijuana Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
25	20	20/0	0%
37.5	20	20/0	0%
62.5	20	2/18	90%
75	20	0/20	100%

Tricyclic Antidepressants Sensitivity Study:

Tricyclic Antidepressants Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
0	20	20/0	0%
500	20	20/0	0%
750	20	20/0	0%
1250	20	4/16	80%
1500	20	0/20	100%

Based on above data, sensitivity of the assay to the 14 analytes is as follows:

Amphetamine:	1000 ng/mL
Barbiturates:	300 ng/mL
Benzodiazepines:	300 ng/mL
Cocaine:	300 ng/mL
Methamphetamine:	1000 ng/mL
MDMA:	500 ng/mL
Opiates300:	300 ng/mL
Opiates2000:	2000 ng/mL
Methadone:	300 ng/mL
Oxycodone:	100 ng/mL
Phencyclidine:	25 ng/mL
Marijuana:	50 ng/mL
Tricyclic Antidepressants:	1000 ng/mL

Precision / Reproducibility:

Reproducibility was determined by replicating tests on five different concentrations of each drug in urine specimens: negative, 50% below cut-off, 25% below cut-off, 25% above cut-off and 50% above cut-off. Each drug test was tested four times daily for five consecutive days with a total 20 assays at each concentration. The data are summarized below:

Amphetamine Precision/Reproducibility Study:

Amphetamine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	1/19	95%
1500	20	0/20	100%

Barbiturates Precision/Reproducibility Study:

Barbiturates Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

Benzodiazepines Precision/Reproducibility Study:

Benzodiazepines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

Cocaine Precision/Reproducibility Study:

Cocaine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	7/13	65%
450	20	0/20	100%

Methamphetamines Precision/Reproducibility Study:

Methamphetamines Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	0/20	100%
1500	20	0/20	100%

MDMA Precision/Reproducibility Study:

MDMA Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
250	20	20/0	100%
375	20	20/0	100%
625	20	0/20	100%
750	20	0/20	100%

Opiates 300 Precision/Reproducibility Study:

Opiates 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	0/20	100%
450	20	0/20	100%

Opiates 2000 Precision/Reproducibility Study:

Opiates 2000 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
1000	20	20/0	100%
1500	20	13/7	65%
2500	20	0/20	100%
3000	20	0/20	100%

Methadone Precision/Reproducibility Study:

Methadone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	20/0	100%
375	20	1/19	95%
450	20	0/20	100%

Oxycodone Precision/Reproducibility Study:

Oxycodone Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
50	20	20/0	100%
75	20	20/0	100%
125	20	3/17	85%
150	20	0/20	100%

Phencyclidine Precision/Reproducibility Study:

Phencyclidine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
12.5	20	20/0	100%
18.75	20	20/0	100%
31.25	20	5/15	75%
37.5	20	0/20	100%

Marijuana Precision/Reproducibility Study:

Marijuana Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
25	20	20/0	100%
37.5	20	20/0	100%
62.5	20	2/18	90%
75	20	0/20	100%

-

Tricyclic Antidepressants Precision/Reproducibility Study:

Tricyclic Antidepressants Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
500	20	20/0	100%
750	20	20/0	100%
1250	20	4/16	80%
1500	20	0/20	100%

The data presented here demonstrates excellent precision/ reproducibility of **Drug Screening Tests** across multiple concentrations of human urine.

Analytical Specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. Analyzing various concentration of each compound by using **Drug Screening Tests**, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

Amphetamine:

Drug Compound	Response equivalent to cutoff in ng/mL
D-Amphetamine	1000
D,L-Amphetamine	2500
L-Amphetamine	50,000
(±) 3,4-Methylenedioxyamphetamine (MDA)	2,000
Ephedrine	>100,000
3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000

Barbiturates

Drug Compound	Response equivalent to cutoff in ng/mL
Secobarbital	300
Phenobarbital	2500
Butalbital	500
Pentobarbital	1500
Amobarbital	2500
Cyclopentobarbital	500
Butethal	800
Barbital	300
Butabarbital	1500

Benzodiazepines

Drug Compound	Response equivalent to cutoff in ng/mL
Oxazepam	300
Alprazolam	200
α-hydroxyalprazolam	1000
Bromazepam	250
Chlordiazepoxide	2500
Clobazam	100
Clonazepam	850
Clorazepate	250
Delorazepam	1600
Diazepam	200
Estazolam	200
Flunitrazepam	300
Lorazepam	1000
Midazolam	1500
Nitrazepam	100
Nordiazepam	400
Temazepam	150
Triazolam	500

Cocaine

Drug Compound	Response equivalent to cutoff in ng/mL
Cocaine	>100,000
Benzoylecgonine	300
Ecgonine HCI	35,000

Methamphetamines

Drug Compound	Response equivalent to cutoff in ng/mL
+/-Methamphetamine	2,000
+Methamphetamine	1,000
3,4-Methylenedioxyethylamphetamine(MDEA)	35,000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	2,000
Ranitidine (Zantac)	>100,000
3,4-Methylenedioxyamphetamine (MDA)	>100,000
D-Amphetamine	>100,000
L-Amphetamine	>100,000
Ephedrine	>100,000

Methylenedioxymethamphetamine

Drug Compound	Response equivalent to cutoff in ng/mL
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500
D-Amphetamine	>100,000
D-Methamphetamine	100,000
3,4-Methylenedioxyethylamphetamine(MDEA)	200
3,4-Methylenedioxyamphetamine (MDA)	2000

Methadone

Drug Compound	Response equivalent to cutoff in ng/mL
Methadone	300
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50,000
Doxylamine	50,000

Opiates 300

Drug Compound	Response equivalent to cutoff in ng/mL
Morphine	300
Codeine	300
Hydrocodone	2,000
Hydromorphone	3,500
Morphine 3-ß-D-glucuronide	300
6-Monoacetylmorphine	600
Normorphone	100,000
Oxycodone	10,000
Oxymorphone	50,000
Thebaine	7,000

Opiates 2000

Drug Compound	Response equivalent to cutoff in ng/mL
Morphine	2,000
Codeine	2,000
Hydrocodone	10,000
Hydromorphone	7,000
Morphine 3-ß-D-glucuronide	2,000
6-Monoacetylmorphine	5,000
Normorphone	100,000
Oxycodone	20,000
Oxymorphone	100,000
Thebaine	70,000

Oxycodone

Drug Compound	Response equivalent to cutoff in ng/mL
Oxycodone	100
Morphine	50,000
Codeine	25,000
Morphine 3-ß-D-glucuronide	50,000
Hydrocodone	1600
Hydromorphone	15,000
Normorphone	100,000
Oxymorphone	1500

Phencyclidine

Drug Compound	Response equivalent to cutoff in ng/mL
Phencyclidine	25
4-Hydroxyphencyclidine	15,000

Marijuana

Drug Compound	Response equivalent to cutoff in ng/mL
11-Nor-Δ^8-THC-9-COOH	50
11-Nor-Δ^9- THC-9-COOH	50
Δ^8-Tetrahydrocannabinol	8,000
Δ^9 –Tetrahydrocannabinol	10,000
Cannabinol	10,000
Cannabidiol	100,000

Tricyclic Antidepressants

Drug Compound	Response equivalent to cutoff in ng/mL
Notriptiline	1,000
Trimipramine	4,500
Amitriptyline	1,000
Promazine	3,000
Desipramine	1,000
Imipramine	1,000
Clomipramine	7,500
Doxepin	3,000
Maprotiline	50,000

Interfering Compounds:
The following compounds in both drug-free urine and drug positive urines with Amphetamine, Cocaine, Barbiturate, Benzodiazepine, Methamphetamine, Mehtylenedioxymethamphetamine, Marijuana, Methadone,Opiates, Oxycodone, Phencyclidine,
Tricyclic Antidepressants show no cross-reactivity when tested with **Drug Screening Tests** at a concentration of 100µg/mL.

Common Substances:

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	1-Phenylephrine
Creatine	β-Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethorphan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride
Erythromycin	Sulindac
Ethanol	Theophylline
Furosemide	Tyramine
Glucose	4-Dimethylaminoantipyrine
Guaiacol Glyceryl Ether	(1R,2S)-(-)-N-Methyl-Ephedrine
Hemoglobin	

Biological Materials:

Albumin	Vitamin (L-Ascorbic Acid)
Bilirubin	Uric Acid
Creatine	Urine pH 4.5-9.0
Hemoglobin	Urine Specific Gravity 1.002-1.035g/mL
Glucose	

(There is a possibility that other substances and/or factors not listed above may interfere with the test and cause false results.)

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