Drug Tests (Strip/Card/Device/Cup)

Package Insert for testing of any combination of the following drugs:
AMP/BAR/BZO/BUP/COC/THC/MTD/mAMP/MDMA/MOP/OPI/OXY/PCP/PPX/TCA
Available with Specimen Validity Tests (S.V.T.) for:
Oxidants/PCC, Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine

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 Tests (Strip/Card/Device/Cup) is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
Amphetamine/AMP 1000	D-Amphetamine	1000 ng/mL
Amphetamine/AMP 300	D-Amphetamine	300 ng/mL
Barbiturates/BAR	Secobarbital	300 ng/mL
Benzodiazepines/BZO	Oxazepam	300 ng/mL
Buprenorphine/BUP	Buprenorphine	10 ng/mL
Cocaine/COC 300	Benzoylecgonine	300 ng/mL
Cocaine/COC 150	Benzoylecgonine	150 ng/mL
Marijuana/THC	Delta-9-THC-COOH	50 ng/mL
Methadone/MTD	Methadone	300 ng/mL
Methamphetamines/mAMP 1000/MET 1000	D-Methamphetamine	1000 ng/mL
Methamphetamines/mAMP 500/MET 500	D-Methamphetamine	500 ng/mL
Methylenedioxymethamphetamine/MDMA	MDMA	500 ng/mL
Opiates 300/MOP/OPI 300	Morphine	300 ng/mL
Opiates 2000/OPI 2000	Morphine	2000 ng/mL
Oxycodone/OXY	Oxycodone	100 ng/mL
Phencyclidine/PCP	Phencyclidine	25 ng/mL
Propoxyphene/PPX	Propoxyphene	300 ng/mL
Tricyclic Antidepressants/TCA	Nortriptyline	1000 ng/mL

Drug Tests (Strip/Card/Device/Cup) 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 Tests (Strip/Card/Device/Cup) 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. **Drug Tests (Strip/Card/Device/Cup)** optionally includes an adulteration strip for testing pH, Specific Gravity and Oxidants/ PCC.

AMPHETAMINE / AMP 1000

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 Tests (Strip/Card/Device/Cup)** yields 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).

AMPHETAMINE / AMP 300

Drug Tests (Strip/Card/Device/Cup) yields a positive result when Amphetamines in urine exceed 300 ng/mL. See AMPHETAMINE / AMP 1000 for summary.

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) to 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 Tests (Strip/Card/Device/Cup)** yields a positive result when secobarbital in urine exceeds 300 ng/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 Tests (Strip/Card/Device/Cup)** yields a positive result when oxazepam in urine exceeds 300 ng/mL.

BUPRENORPHINE / BUP

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days. **Drug Tests (Strip/Card/Device/Cup)** yields a positive result when Buprenorphine in urine exceeds 10 ng/mL.

COCAINE / COC 300

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 Tests (Strip/Card/Device/Cup)** yields a positive result when the Cocaine metabolite in urine exceeds 300 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

COCAINE / COC 150

Drug Tests (Strip/Card/Device/Cup) yields a positive result when the Cocaine metabolite in urine exceeds 150 ng/mL. See COCAINE / COC 300 for summary.

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 remains detectable for 3-10 days after smoking. **Drug Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINES / mAMP 1000 / MET 1000

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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of Methamphetamine in urine exceeds 1000 ng/mL.

METHAMPHETAMINES / mAMP 500 / MET 500

Drug Tests (Strip/Card/Device/Cup) yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL. See METHAMPHETAMINE / mAMP 1000 for summary.

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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of MDMA in urine exceeds 500 ng/mL.

OPIATES 300 / MOP / OPI 300

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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of Opiates in urine exceeds 300 ng/mL.

OPIATES 2000 / OPI 2000

Drug Tests (Strip/Card/Device/Cup) yields a positive result when the concentration of Opiates in urine exceeds 2000 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA). See OPIATES 300 / MOP for summary.

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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of Oxycodone in urine exceeds 100 ng/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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of Phencyclidine in urine exceeds 25 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

PROPOXYPHENE / PPX

Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration. **Drug Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of propoxyphene level in urine exceeds 300 ng/mL.

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 Tests (Strip/Card/Device/Cup)** yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL.

S.V.T. SUMMARY

The strips contain chemically treated reagent pads. Three to five minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help to assess the integrity of the urine sample.

WHAT IS ADULTERATION?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

- **Oxidants/PCC (Pyridinium chlorochromate)** tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium chlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.[6] Normal human urine should not contain oxidants of PCC.
- **Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- **pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- **Nitrite** tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[9] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- **Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassay tests.[7] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[8] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to "flush" the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE OF TEST

Drug Tests (Strip/Card/Device/Cup) 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.

REAGENTS

Drug Tests (Strip/Card/Device/Cup) contains 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, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants / PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

MATERIALS PROVIDED

- Drug Tests (Strip/Card/Device/Cup)
- Product insert
- Security Seal
- Procedure Card
- Adulteration color card (Optional)

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- External positive and negative controls

PRECAUTIONS

1. For *forensic* use only.
2. For *in vitro* diagnostic use only.
3. Do not use after the expiration date.
4. The drug tests 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 drug tests should be discarded according to federal, state and local regulation.

STORAGE AND STABILITY

Store **Drug Tests (Strip/Card/Device/Cup)** in the sealed pouch at 2℃ to 30℃. The drug tests is stable through the expiration date printed on the sealed pouch. The drug tests must remain in the sealed pouch until use. If store at 2℃ to 8℃, allow the drug tests to reach room temperature (15℃ to 30℃) before performing the test. Dot not freeze, do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

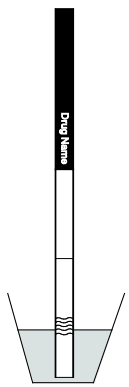
Fresh urine specimens should be collected directly into a clean and dry container. Urine collected at any time of the day may be used for testing. Urine specimen exhibiting visible precipitates should be centrifuged, filtered or allowed the precipitates to settle to obtain a clear specimen for testing.

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°C) prior to using.

TEST PROCEDURE

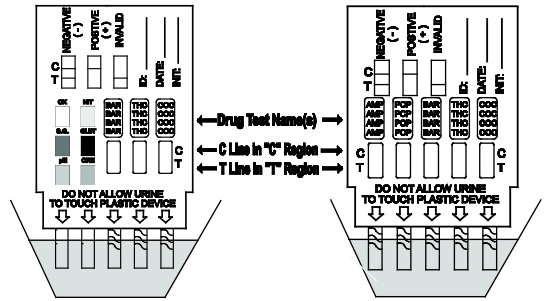
For Drug Test Strip:

1. Equilibrate the test strip, urine specimens or external controls to room temperature (15 -30°C) prior to testing.
2. Remove the test strip from the sealed pouch and dip the end of the strip into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip just below the top line of the wave line on the test strips.
3. Place the test strip on a flat dry surface.
4. Read the results at 5 to 10 minutes.



For Drug Test Card:

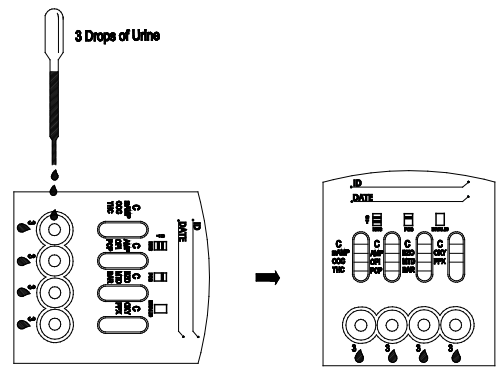
1. Equilibrate the test card, urine specimens or external controls to room temperature (15 -30°C) prior to testing.
2. Remove the test card from the sealed pouch and dip the card into the specimen for at least 15 seconds to 20 seconds or until migration occurs. Immerse the strip (s) of the test card just below the top line of the wave line on the test strips; do not dip the card above the top line.
3. Place the test card on a flat dry surface.
4. Read the adulteration strips between 3 to 5 minutes (when applicable) by comparing the colors in the adulteration pads to the enclosed color chart. If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adultered specimens. We recommend not to interpret the drug test results and suggest you to retest the urine by using another specimen.
5. Read the results at 5 to 10 minutes.



For Drug Test Device:

Allow the test device, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 μL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line (s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.

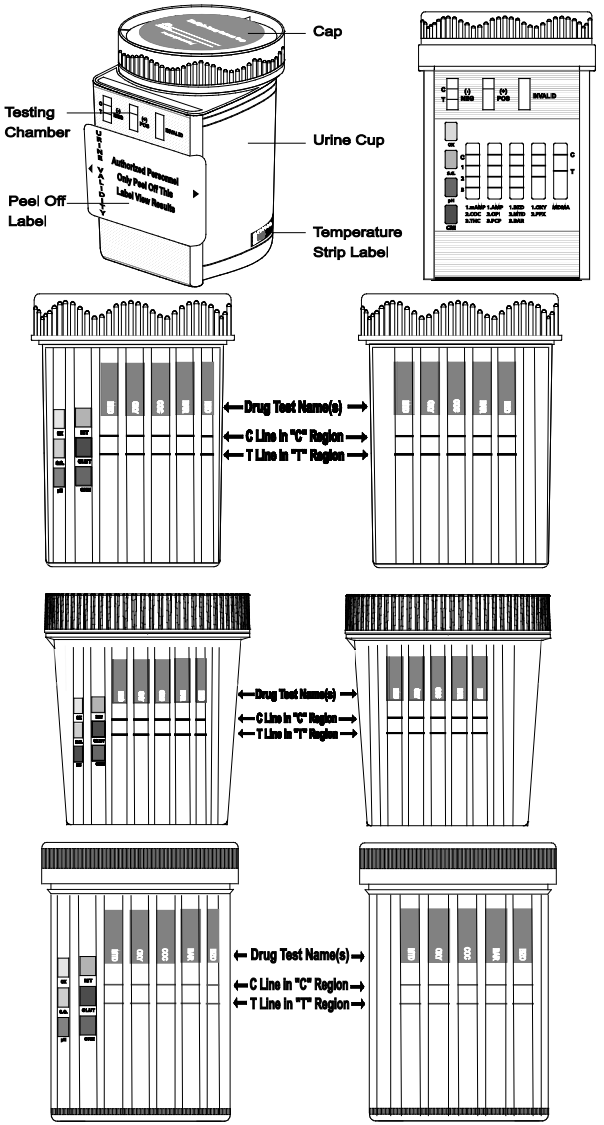


For Drug Test Cup:

Allow the cup, urine specimen, and/or controls to reach room temperature (15-30°C) before testing.

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup and secure the cap tightly.
3. If the temperature strip is included with Drug Test Cup, please read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 90–100℉ (33-38℃).
4. Place the cup on a flat surface.
5. Date and initial the security seal, and place the security seal on the cap.
6. Peel off the label on the cup to view the results.
7. If adulteration test is included on the test cup, read the adulteration test results between 2 to 5 minutes. See the color chart for interpretation. If the specimen indicates adulteration, we recommend not to interpret the drug test results and either retest the urine or collect another specimen.

8. **Read the test results at 5 minutes.** See the illustration below. For detailed operation instructions, please refer to the Procedure Card.



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.

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.

ADULTERATION INTERPRETATION

(Please refer to the color chart, if applicable)

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

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 drug tests.
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.

S.V.T. ADULTERATIONS LIMITATIONS

1. The adulteration tests included with the product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an "all-inclusive" representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
5. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
6. Glutaraldehyde: is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.
7. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

LIMITATIONS

1. **Drug Tests (Strip/Card/Device/Cup)** 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 drug tests.
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 Tests (Strip/Card/Device/Cup)** 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 1000	AMP 300	BAR	BZO	BUP	COC 300	COC 150
Positive Agreement	100%	100%	98%	97%	100%	100%	97.5%
Negative Agreement	98%	100%	98%	97%	100%	100%	97.5%
Total Agreement	99%	100%	98%	97%	100%	100%	97.5%

	THC	MTD	mAMP 1000	mAMP 500	MDMA	MOP	OPI
Positive Agreement	100%	98%	100%	100%	97%	100%	100%
Negative Agreement	98%	97%	98%	100%	97%	100%	100%
Total Agreement	99%	97.5%	99%	100%	97%	100%	100%

	OXY	PCP	PPX	TCA
Positive Agreement	98%	100%	98%	100%
Negative Agreement	98%	98%	98%	98%
Total Agreement	98%	99%	98%	99%

% Agreement with GC/MS

	AMP 1000	AMP 300	BAR	BZO	BUP	COC 300	COC 150
Positive Agreement	100%	95%	98%	97%	95%	100%	100%
Negative Agreement	98%	100%	98%	97%	100%	100%	97.5%
Total Agreement	99%	97.5%	98%	97%	97.5%	100%	99%

	THC	MTD	mAMP 1000	mAMP 500	MDMA	MOP	OPI
Positive Agreement	100%	98%	100%	100%	97%	100%	100%
Negative Agreement	98%	97%	98%	97.5%	97%	100%	100%
Total Agreement	99%	97.5%	99%	99%	97%	100%	100%

	OXY	PCP	PPX	TCA*
Positive Agreement	98%	100%	98%	100%
Negative Agreement	98%	98%	98%	98%
Total Agreement	98%	99%	98%	99%

TCA*: TCA was based on HPLC data. BUP**: BUP was based on LC/MS data.

Sensitivity:

Sensitivity of **Drug Tests (Strip/Card/Device/Cup)** 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:

Drug concentration Cut-off Range	n	AMP 1000		AMP 300		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	13	7	20	0	20	0
+25% Cut-off	20	1	19	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	BUP		COC 300		COC 150		THC	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	20	0	20	0
+25% Cut-off	20	0	20	7	13	0	20	2	18
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	MTD		mAMP 1000		mAMP 500		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	20	0	20	0
+25% Cut-off	20	1	19	0	20	0	20	0	20
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	MOP		OPI		OXY		PCP	
		-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	13	7	20	0	20	0
+25% Cut-off	20	0	20	0	20	3	17	5	15
+50% Cut-off	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	PPX		TCA	
		-	+	-	+
0% Cut-off	20	20	0	20	0
-50% Cut-off	20	20	0	20	0
-25% Cut-off	20	20	0	20	0
+25% Cut-off	20	4	16	4	16
+50% Cut-off	20	0	20	0	20

Based on above data, sensitivity of the assay to the 18 analytes is as follows:

Amphetamine 1000:	1000 ng/mL	Methamphetamine 1000:	1000 ng/mL
Amphetamine 300:	300 ng/mL	Methamphetamine 500:	500 ng/mL
Barbiturates:	300 ng/mL	MDMA:	500 ng/mL
Benzodiazepines:	300 ng/mL	Opiates 300:	300 ng/mL
Buprenorphine:	10 ng/mL	Opiates 2000:	2000 ng/mL
Cocaine 300:	300 ng/ mL	Oxycodone:	100 ng/mL
Cocaine 150:	150 ng/ mL	Phencyclidine:	25 ng/mL
Marijuana:	50 ng/mL	Propoxyphene:	300 ng/mL
Methadone:	300 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 1000 Precision /Reproducibility Study:

Amphetamine 1000 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%

Amphetamine 300 Precision /Reproducibility Study:

Amphetamine 300 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	18/2	90%
375	20	0/20	100%
450	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%

Buprenorphine Precision/Reproducibility Study:

Buprenorphine Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
5	20	20/0	100%
7.5	20	20/0	100%
12.5	20	1/19	95%
15	20	0/20	100%

Cocaine 300 Precision/Reproducibility Study:

Cocaine 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	7/13	65%
450	20	0/20	100%

Cocaine 150 Precision /Reproducibility Study

Cocaine 150 Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Precision (%)
0	20	20/0	100%
150	20	20/0	100%
225	20	18/2	90%
375	20	0/20	100%
450	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%

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%

Methamphetamines 1000 Precision/Reproducibility Study:

Methamphetamines 1000 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%

Methamphetamines 500 Precision /Reproducibility Study:

Methamphetamines 500 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%

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%

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%

Propoxyphene Precision /Reproducibility Study:

Propoxyphene 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	4/16	80%
450	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 Tests (Strip/Card/Device/Cup)** 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 Tests (Strip/Card/Device/Cup)**, 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:

Drug Compound	Response equivalent to cutoff in ng/mL
AMPHETAMINE 1000 (AMP)	
D-Amphetamine	1000
D,LAmphetamine	2500
L-Amphetamine	50000
(±)3,4-Methylenedioxyamphetamine (MDA)	2000
Ephedrine	>100000
3,4-Methylenedioxythylamphetamine (MDEA)	>100000
AMPHETAMINE 300 (AMP)	
D-Amphetamine	300
D,L-Amphetamine	850
L-Amphetamine	17500
D-Methamphetamine	100000
L-Methamphetamine	>100000
(±) 3,4-Methylethyenedioxyamphetamine (MDA)	650
Ephedrine	>100000
3,4-Methylenedioxyethyamphetamine (MDEA)	>100000
BARBITURATES (BAR)	
Secobarbital	300
Phenobarbital	2500
Butalbital	500
Pentobarbital	1500
Amobarbital	2500
Cyclopentobarbital	500
Butethal	800
Barbital	300
Butabarbital	1500
BENZODIAZEPINES (BZO)	
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
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	15
Buprenorphine-3-D-glucuronide	12.5
Norbuprenorphine-3-D-glucuronide	175
Morphine-3-D-glucuronide	100000
Morphine	>100000
Oxymorphone	>100000
Hydromorphone	>100000
COCAINE 300 (COC)	
Cocaine	>100000
Benzoylecgonine	300
Ecgonine HCl	35000
COCAINE 150 (COC)	
Cocaine	>100000
Benzoylecogonine	150
Ecgonine HCl	17000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9-COOH	50
11-nor-Δ^9-THC-9-COOH	50
Δ^8-Tetrahydrocannabinol	8000
Δ^9-Tetrahydrocannabinol	10000
Cannabinol	10000

Cannabidiol	100000
METHADONE (MTD)	
Methadone	300
(±)2-Ethy1-1,5-dimethy1-3,3-diphenylpyrrolinium	50000
Doxylamine	50000
METHAMPHETAMINES 1000 (mAMP/MET)	
+/-Methamphetamine	2000
+Methamphetamine	1000
3,4-Methylenedioxyethylamphetamine(MDEA)	35000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	2000
Ranitidine(Zantac)	>100000
3,4-Methylenedioxyamphetamine (MDA)	>100000
D-Amphetamine	>100000
L-Amphetamine	>100000
Ephedrine	>100000
METHAMPHETAMINES 500 (mAMP/MET)	
(±) Methamphetamine	1000
(+) Methamphetamine	500
(±) 3,4-Methylenedioxymethamphetamine (MDMA)	1000
Ranidine (Zantac)	> 100000
3,4-Methylenedioxyamphetamine (MDA)	> 100000
D-Amphetamine	> 100000
L-Amphetamine	> 100000
Ephedrine	> 100000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500
D-Amphetamine	>100000
L-Methamphetamine	100000
3,4-Methylenedioxyethylamphetamine (MDEA)	200
3,4-Methylenedioxyamphetamine (MDA)	2000
OPIATE 300 (MOP/OPI 300)	
Morphine	300
Codeine	300
Hydrocodone	2000
Hydromorphone	3500
Morphine 3-β-D-glucuronide	300
6-Monoacetylmorphine	600
Normorphone	100000
Oxycodone	10000
Oxymorphone	50000
Thebaine	7000
OPIATE 2000 (OPI 2000)	
Morphine	2000
Codeine	2000
Hydrocodone	10000
Hydromorphone	7000
Morphine 3-β-D-glucuronide	2000
6-Monoacetylmorphine	5000
Normorphone	100000
Oxycodone	20000
Oxymorphone	100000
Thebaine	70000
OXYCODONE (OXY)	
Oxycodone	100
Morphine	50000
Codeine	25000
Morphine 3-β-D-glucuronide	50000
Hydrocodone	1600
Hydromorphone	15000
Normorphone	100000
Oxymorphone	1500
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	15000
PROPOXYPHENE (PPX)	
Propoxyphene	300
Norpropoxyphene	7500
Methadone	> 100000
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Notriptiline	1000
Trimipramine	4500
Amitriptyline	1000
Promazine	3000
Desipramine	1000
Imipramine	1000
Clomipramine	7500
Doxepin	3000
Maprotiline	50000

Interfering Compounds:

The following compounds in both drug-free urine and drug positive urines with Amphetamine, Barbiturate, Benzodiazepine, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamines, Mehtylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants show no cross-reactivity when tested with **Drug Tests (Strip/Card/Device/Cup)** at a concentration of 100 μg/mL**.**

Common Substances:

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

Biological Materials:

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