Drug Screening Test Cup

Package Insert for testing of any combination of the drugs:

AMP/AR/BBZ/BUP/COC/THC/MIT/MDMA/OPI300/OXY/PCP/PPT/TCA

Available with Specimen Validity Tests (S.V.T.) for: Oxidant, H2O2, Nitrite, Lactate, and BDO (blood alcohol) 

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.

INSTRUCTIONS

Drug Screening Test Cup is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cutoff concentrations:

**Test Name**

**Calibrator**

**Cut-off**

**D-Amphetamine/AMP 1000**

D-Amphetamine

100 ng/mL

**Barbiturates/BAR**

Secobarbital

500 ng/mL

**Benzodiazepines/BZO**

Oxazepam

500 ng/mL

Buprenorphine

25 ng/mL

Cocaine/COC 300

Buprenorphine

100 ng/mL

**Cocaine/COC 150**

Buprenorphine

50 ng/mL

**Methamphetamine/MET 1000**

Methamphetamine

500 ng/mL

**Methylenedehydromethamphetamine/MDMA**

MDMA

500 ng/mL

**Opiates 300/OPI 300**

Opiates

300 ng/mL

**Opiates 300/OPI**

Opiates

300 ng/mL

**Oxycodone/OXY**

Oxycodone

100 ng/mL

**Phencyclidine/PCP**

Phencyclidine

100 ng/mL

**Propoxyphene/PPT**

Propoxyphene

500 ng/mL

**Ropivacaine/RNO**

Ropivacaine

500 ng/mL

**Tricyclic Antidepressants/TCA**

TCA

1000 ng/mL

**Drug Screening Test Cup**

Drugs may not be detected in urine if the concentration of the drug is below the cutoff level. Strips must not 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.

**SPECIAL EXPLANATION OF THE TEST**

Drug Screening Test Cup is an easy, fast, qualitative, visually readable competitive 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 Screening Test Cup optionally includes an adulteration strip for testing pH, Specific Gravity and Opiates.

**AMPETHAMINE / AMP 1000**

Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, ravenous hunger, and overall euphoria or “high.” They are chemically related to the human body’s natural catecholamines: epinephrine and norepinephrine. Large doses and extended usage can result in tolerance, high heart rates, and associated adverse effects. Amplifies the amphetamine generally 3 – 6 hours following use, and the drug has a half-life of 24 -24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deamintiated derivatives. Drug Screening Test Cup yield a positive result when Amphetamines in urine exceed 1000 ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

**BENZODIAZEPINES / BZO**

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their property by an ability to bind to the GABA receptors, thus allowing a higher concentration of GABA, resulting in respiratory depression, blockade of adrenal cortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (in which it is conjugated to glucuronic acid). Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Drug Screening Test Cup yields a positive result when the concentration of Benzodiazepines in urine exceeds 300ng/mL.

**BARBITURATES / BAR**

Secobarbital is a 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. In the presence of alcohol, barbiturates potentiate their own depression and power and lead to its abuse. Drug Screening Test Cup yields a positive result when secobarbital 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 for opioids. Treatment of a substitution 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 250ng/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 Screening Test Cup yields a positive result when Buprenorphine in urine exceeds 10ng/mL.

**COCAIN / COC 300**

Cocaine is an alkaloid present in Coca leaves (Erythroxyla coca). Its pharmacological properties, such as stimulating and ephedric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In the presence of alcohol, Barbiturates potentiate their own depression and power and lead to its abuse. Drug Screening Test Cup yields a positive result when the concentration of Opiates in urine exceeds 300ng/mL.

**Cocaine/COC 150**

Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In the presence of alcohol, Barbiturates potentiate their own depression and power and lead to its abuse. Drug Screening Test Cup yields a positive result when the concentration of Cocaine metabolite in urine exceeds 150ng/mL. See COCAINE / COC 300 for summary.

**METHAMPHETAMINES / MET 1000**

Methamphetamine use.

Methamphetamine is a stimulant drug that strongly activates certain cells 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, intranasally, or intravenously. The drug reaches its peak in 1 to 2 hours following use, and the drug has a half-life of 24 -24 hours in the body. About 30% of Methamphetamine is excreted in the urine in unchanged form, with the remainder as hydroxylated and deamintiated derivatives. Drug Screening Test Cup yield a positive result when the concentration of Methamphetamine in urine exceeds 1000 ng/mL.

**METHYLENEDIOXYMETHAMPHETAMINE / MDMA**

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all 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 orally or intravenously. Drug Screening Test Cup yields a positive result when the concentration of MDMA in urine exceeds 500ng/mL.

**OPIATES / OPI 300**

Opiates refer to any drug that is derived from the opium poppy, including the natural alkaloids codeine, morphine, and papaverine. Opiates are often self-administered by intravenous drug users. Opiates can also be found in urine of addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Opiates are as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Opiates and Norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 250ng/ml in abuse situations. The plasma half life of Opiates 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 Screening Test Cup yields a positive result when the concentration of Opiates in urine exceeds 300ng/mL.

**OPIATES 2000 / OPI 300**

Drug Screening Test Cup yields 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). See OPIATES 300 / OPI 300 for summary.

**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 intravenous PCP are very minor, but its effects on the brain can cause a variety of nervous system stimulants that produce alertness, wakefulness, increased energy, increased heart rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of PCP-induced (PCP) in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) could develop tolerances and physical dependence and lead to its abuse. PCP can be found in urine in 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 Test Cup yields a positive result when the concentration of Phencyclidine in urine exceeds 100ng/mL, which is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Service Administration (SAMHSA, USA).

**PPOPXYPHENE / PPX**

Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can lead to respiratory depression, coma, and death. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration. Drug Screening Test Cup yields a positive result when the concentration of propoxyphene in urine exceeds 500ng/mL.

**TRICYCLIC ANTIDEPRESSANTS / TCA**

Tricyclic Antidepressants are a group of antidepressants that are commonly used for

excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Drug Screening Test Cup yields a positive result when the concentration of Methamphetamine in urine exceeds 1000ng/mL.
Buffers and non-reactive ingredients

Buffer and non-reactive ingredients

Creatinine

Nitrates

Glutaraldehyde

pH

Specific gravity

Oxidants / PCC

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.

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 UrinAid) is a commonly used adulterant.

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. 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 Whizzers.

They work by oxidizing the major cannabinoid THC-COOH.

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 UranAid and UrinAid contain compounds that contain glutaraldehyde which may cause false negative results by disrupting the enzyme used in some immunoassays. Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indication of adulteration.

- Creatinine is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine. 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 with a normal or elevated specific gravity of Creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

PRINCIPLE OF TEST

Drug Screening Test 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 test area, the sample 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 be bound to the drug-antibody conjugate 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, the drug-antibody conjugates will react 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 Screening Test 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, Methyleneoxyxymethylamine, Morphine, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

S.V.T. REAGENTS

Adulteration Pad Reactive indicator Buffers and non-reactive ingredients

Creatinine 0.04% 99.96%

Nitrate 0.02% 99.98%

Glutaraldehyde 0.02% 99.98%

pH 0.06% 99.94%

Specific gravity 0.07% 99.75%

Oxidants / PCC 0.56% 99.64%

MATERIALS PROVIDED

- Drug Test Cup
- Product insert
- Security Seal
- Procedure card
- Authorized 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. All used cup should be discarded according to federal, state and local regulation.

5. 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 to the color chart.

6. Peel off the label on the cup to view the results.

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 is not in the metabolizable 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 for applicable colors)

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 CONTROLS

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 a quality control procedure 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. 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.

5. Glutaraldehyde: is not normally found in urine. However, certain metabolic abnormalities such as diabetes (fasting, uncontrolled diabetes) or high protein diets may interfere with the test results.

6. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

LIMITATIONS

1. Drug Screening Test 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 device.

4. The urine specimen with bacterial contamination should not be used for testing, as...
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**

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/mL)</th>
<th>Methamphetamine 1000</th>
<th>Methadone 1000</th>
<th>MDMA</th>
<th>Opiates 300</th>
<th>Opiates 2000</th>
<th>Oxycodone 300</th>
<th>Amphetamine 1000</th>
<th>Methadone Concentration (ng/mL)</th>
<th>Methamphetamine Concentration (ng/mL)</th>
<th>Phencyclidine Concentration (ng/mL)</th>
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<tbody>
<tr>
<td><strong>Accuracy</strong></td>
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</tbody>
</table>

**Precision / Reproducibility**

Based on Amphetamine 1000: 1000 ng/mL, Methamphetamine 1000: 1000 ng/mL, Methadone 1000: 1000 ng/mL, Barbiturates: 300 ng/mL, MDMA: 5000 ng/mL, Benzoylepine: 300 ng/mL, Opiates 300: 300 ng/mL, Buprenorphine: 10 ng/mL, Opiates 2000: 2000 ng/mL, Cocaine 500: 300 ng/mL, Oxycocaine: 100 ng/mL, Cocaine 150: 150 ng/mL, Phencyclidine: 25 ng/mL, Marijuana: 50 ng/mL, Propoxyphene: 300 ng/mL, Methadone: 300 ng/mL.

Methadone: 300 ng/mL, Tricyclic Antidepressant: 1000 ng/mL.

**Sensitivity**

Sensitivity of Drug Screening Test 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:

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>AMP 100</th>
<th>AMP 300</th>
<th>BUP</th>
<th>MET</th>
<th>MTD</th>
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<tr>
<td>&lt;5% Cut-off</td>
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<th>BUP</th>
<th>COC 100</th>
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<table>
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<th>MET 300</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>COC</th>
<th>COC 300</th>
<th>COC 100</th>
<th>TCA</th>
</tr>
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<tbody>
<tr>
<td>&lt;5% Cut-off</td>
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<td>5% Cut-off</td>
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<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>&lt;10% Cut-off</td>
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<td>10</td>
<td>10</td>
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<tr>
<td>10% Cut-off</td>
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<td>10</td>
<td>10</td>
<td>10</td>
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<tr>
<td>&lt;15% Cut-off</td>
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<tr>
<td>15% Cut-off</td>
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<td>10</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>
Tricyclic Antidepressants Precision/Reproducibility Study:

Drug Compound | Response equivalent to cutoff in ng/mL |
--- | --- |
MADURPHAN \((\text{TCA})\) | 90 |
\(10\)-nor-E-\(\text{TCA}\)-3-\(\text{COOH}\) | 90 |
\(10\)-nor-E-\(\text{TCA}\)-3-\(\text{COOH}\) | 90 |
\(\text{Trimipramine}\) | 10000 |
\(\text{Tofranil}\) | 10000 |
\(\text{Atarax}\) | 10000 |

The data presented demonstrates excellent precision and reproducibility of Drug Screening Test 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 concentrations of each compound by using Drug Screening Test 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:

### Interfering Compounds:

The following compounds in both drug-free urine and drug-positive urines with Amphetamine, Cocaine, Barbiturate, Benzodiazepine, Buprenorphine, Marijuana, Methadone, Methylenedioxymethamphetamine, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants show no cross-reactivity when tested with Drug Screening Test Cup at a concentration of 100ng/mL.

### Common Substances:

Alcohol, Amphetamines, Xylocaine, Acetone, 1,4-dihydropyridine, 1,2-dimethoxy-2,3-dimethyladamantan, 1,3-dimethyl-2-phenylpropene, 1,3-dimethyl-2-phenylpropene, 1,3-dimethyl-2-phenylpropene and 1,3-dimethyl-2-phenylpropene.

### Biological Materials:

Albumin, Acetaminophen, Acetylcholine, Acetylcholine, Acetylcholine, Acetylcholine, Acetylcholine,

### Bibliography: