Barbiturates / BAR 300

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 Barbiturates could develop tolerance and physical dependence and lead to its abuse. Drug Tests (Card/Device/Cup) yields a positive result when secobarbital in urine exceeds 300 ng/mL.

Benzodiazepines / BZO 300

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, reduced appetite, and a sense of increased energy and power. Methadone is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10 to 20 % of Methadone is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methadone use. Drug Tests (Card/Device/Cup) yields a positive result when the concentration of Methadone in urine exceeds 300 ng/mL.

Methamphetamine / 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 dopamine 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 usage, and the drug has a half-life of 10-12 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 (Card/Device/Cup) yields a positive result when the 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).

AMPHETAMINE / AMP 300

Drug Tests (Card/Device/Cup) yields a positive result when the concentration of AMPHETAMINE in urine exceeds 300 ng/mL. See AMPHETAMINE / AMP 1000 for summary.

Benzodiazepines / BZO 300

[yields a positive result when the concentration of BENZODIAZEPINES in urine exceeds 300 ng/mL.

Drug Tests (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 Services Administration (SAMHSA, USA).

MARIJUANA / THC 50

Drug Tests (Card/Device/Cup) yields a positive result when the concentration of THC-COOH in urine exceeds 40 ng/mL. See MARIJUANA / THC 30 for summary.
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 leading to suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of Oxycodone addiction include extreme loss of appetite and weight loss, 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 (Card/Device/Cup) yields a positive result when the concentration of Oxycodone in urine exceeds 100 ng/mL.

PHENCYCLIDINE / PCP, 99.93%

Phencyclidine, commonly known as PCP or “angels dust” is used primarily as recreational drug due to its hallucinogenic effects. It is 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) can result in death due to convulsions, heart and lung failure and coma. Large doses of Phencyclidine (PCP) can result in severe bleeding. The half-life of TCA ranges from 1 to 24 hours. Phencyclidine reaches its peak in 1 to 2 hours after oral administration. Drug Tests (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 Services Administration (SAMHSA, USA).

PROPOXYPHENE / PXP, 99.98%

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 (Card/Device/Cup) yields a positive result when the concentration of propoxyphene level in urine exceeds 300 ng/mL. Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscular injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hyperactivity, seizures, and EKG changes. The half-life of TCA ranges from a few hours to several days. The commonly used TCAs are excrated with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been for screening the abuse of TCAs. Drug Tests (Card/Device/Cup) yields a positive result when the concentration of Nortriptyline in urine exceeds 1,000 ng/mL. 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 chemicals or reducing the drugs present in the urine. Dilution may also be employed in an attempt to produce a false negative drug test result. 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 oxidents/PCC, nitrates 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 Urine Luck) is a commonly used adulterant. Normal human urine should not contain oxidents of PCC.

- **Specific gravity** tests for sample dilution. The normal range is from 1.005 to 1.030. Values outside of this range may be the result of specimen dilution or adulteration.
- **pH Tests** for the presence of acids or bases. Normal urine pH 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. 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. 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. A person may attempt to fail a test by drinking excessive amounts of water with creatine supplements such as creatine flux the system. Creatinine is a specific gravity of 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 (Card/Device/Cup) is a competitive binding immunoassay in which drug 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 T line. In the absence of drug, the T line will not be formed, which is indicated 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 (Card/Device/Cup) contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold conjugates at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methyleneoxydextroamphetamine, Morphine, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants.

**S.V.T. REAGENTS**

- Adulteration Card
- Reactive indicator
- Buffers and non-reactive ingredients

**Adulteration Card**

<table>
<thead>
<tr>
<th>Oxidants / PCC</th>
<th>0.36%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Gravity</td>
<td>0.25%</td>
</tr>
<tr>
<td>pH</td>
<td>99.75%</td>
</tr>
<tr>
<td>Nitrite</td>
<td>99.93%</td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>99.98%</td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.04%</td>
</tr>
</tbody>
</table>

**MATERIALS PROVIDED**

- Drug Tests (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 regulations.

**STORAGE AND STABILITY**

Store Drug Tests (Card/Device/Cup) in the sealed pouch at 2°C to 30°C. 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°C to 8°C, allow the drug tests to reach room temperature (15°C to 30°C) before performing the test. Do 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 out to obtain a clear specimen for testing.

For best results, use 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 Mini Cup**

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimens in the cup and secure the cup tightly.
3. Place the cup on a flat surface.
4. Date and initial the security seal, and place the security seal on the cap.
5. Peel off the label on the cup to view the results.
6. 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.
7. Read the test results at 5 minutes.

For most results, the results can be stable up to 1 hour, however, some urine samples fall into the drug concentrations >25% to >50%, those results can not be stable up to 1 hour.

**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. Inverse 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 adulterated 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 cup tightly.
3. If the temperature strip is included with Drug Test Cup, please read urine temperature (15-30°C) prior to testing.
4. Place the cup on a flat surface.
5. Peel off the label on the cup to view the results.
6. Test does not distinguish between drugs of abuse and certain medications.
7. Test does not detect drugs in the urine in the absence of endogenous levels of analytes.
8. Certain foods or food supplements may cause a false positive result. Avoid eating or drinking before testing, and for at least 2 hours after testing.
9. Drug concentrations +25% to +50%, those results can not be stable up to 1 hour.

INTERPRETATION OF RESULTS
Positive: One colored line appears in the Control zone (C). No line appears in the Test zone (T).
Negative: One colored line appears in the Control zone, and another colored line appears in the Test zone.
Invalid: No line appears in the Control zone. If no C line or no C line and T line develop within 3 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
(For Drug Test Card/Device/Cup)
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 must be repeated with a new drug test.
2. External Quality Control: Control materials are not supplied with this kit. 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 within the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

LIMITATIONS
1. Drug Tests (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 test 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 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 detect 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 (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.
<table>
<thead>
<tr>
<th>Drug Tests (Card/Device/Cup)</th>
<th>Concentration (ng/mL)</th>
<th>Reproducibility</th>
<th>Precision/Reproducibility Study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>Total numbers of Determinations:</td>
<td>Results</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
<tr>
<td>Methadone 300</td>
<td>100 ng/mL</td>
<td>20/0</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Sensitivity:**
- Sensitivity of Drug Tests (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 results in total number of determinations. The results were summarized as the following:

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>n</th>
<th>AMP100</th>
<th>AMP300</th>
<th>BAR</th>
<th>BZO</th>
<th>GDP</th>
<th>TCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10% Cut-off</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>20% Cut-off</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>50% Cut-off</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>100% Cut-off</td>
<td>20</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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

### Barbiturates

- **Concentration (ng/mL):** 250 ng/mL
- **Reproducibility:** 100% (Results: 20/0, Precision: 100%)
- **Precision/Reproducibility Study:**
  - **Barbiturates Precision/Reproducibility Study:**
    - **Concentration (ng/mL):** 250 ng/mL
    - **Total numbers of Determinations:** 20/0
    - **Results:** 100%
    - **Precision:** 100%

### Benzodiazepines

- **Concentration (ng/mL):** 300 ng/mL
- **Reproducibility:** 100% (Results: 20/0, Precision: 100%)
- **Precision/Reproducibility Study:**
  - **Benzodiazepines Precision/Reproducibility Study:**
    - **Concentration (ng/mL):** 300 ng/mL
    - **Total numbers of Determinations:** 20/0
    - **Results:** 100%
    - **Precision:** 100%

- **Methamphetamine 300 Precision/Reproducibility Study:**
  - **Concentration (ng/mL):** 300 ng/mL
  - **Total numbers of Determinations:** 20/0
  - **Results:** 100%
  - **Precision:** 100%

### Methamphetamine

- **Concentration (ng/mL):** 1000 ng/mL
- **Reproducibility:** 100% (Results: 20/0, Precision: 100%)
- **Precision/Reproducibility Study:**
  - **Methamphetamine 1000 Precision/Reproducibility Study:**
    - **Concentration (ng/mL):** 1000 ng/mL
    - **Total numbers of Determinations:** 20/0
    - **Results:** 100%
    - **Precision:** 100%

### Methadone

- **Concentration (ng/mL):** 300 ng/mL
- **Reproducibility:** 100% (Results: 20/0, Precision: 100%)
- **Precision/Reproducibility Study:**
  - **Methadone Precision/Reproducibility Study:**
    - **Concentration (ng/mL):** 300 ng/mL
    - **Total numbers of Determinations:** 20/0
    - **Results:** 100%
    - **Precision:** 100%

### Cocaine

- **Concentration (ng/mL):** 150 ng/mL
- **Reproducibility:** 100% (Results: 20/0, Precision: 100%)
- **Precision/Reproducibility Study:**
  - **Cocaine Precision/Reproducibility Study:**
    - **Concentration (ng/mL):** 150 ng/mL
    - **Total numbers of Determinations:** 20/0
    - **Results:** 100%
    - **Precision:** 100%
The data presented here demonstrates excellent precision/ reproducibility of Drug Tests (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 (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

<table>
<thead>
<tr>
<th>Drug Compound</th>
<th>Response equivalent to</th>
<th>Test</th>
<th></th>
</tr>
</thead>
</table>

### Common Substances:

<table>
<thead>
<tr>
<th>Common Substances</th>
<th>Drug Tests (Card/Device/Cup)</th>
</tr>
</thead>
</table>

### Interfering Compounds:

- **The following compounds in both drug-free urine and drug positive urines with Amphetamine, Barbiturate, Benzo diaze pine, Buprenorphine, Cocaine, Mari juana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opal es, Oxycodone, Phenylcyclidine, Propoxyphene, Tricyclic Antidepressants show no cross-reactivity when tested with Drug Tests (Card/Device/Cup) at a concentration of 100 μg/mL.**

### Bibliography:


### Material Biologicals:

<table>
<thead>
<tr>
<th>Biological Materials</th>
<th>Substance</th>
</tr>
</thead>
</table>

### Table:

<table>
<thead>
<tr>
<th>Drug Compound</th>
<th>Response equivalent to</th>
<th>Test</th>
<th></th>
</tr>
</thead>
</table>

---

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