The CLIAwaived, Inc. Rapid Dip Drug Test (RDDT) test is an in vitro screen test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentrations:

- COC: Benzoylecgonine (300 ng/ml)
- OPI: Morphine (2000 ng/ml)
- OPI: Morphine (300 ng/ml)
- MET: Methamphetamine (1000 ng/ml)
- MET: Methamphetamine (500 ng/ml)
- THC: 11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid (50 ng/ml)
- AMP: Amphetamine (1000 ng/ml)
- PCP: Phencyclidine (25 ng/ml)
- BZO: Oxazepam (300 ng/ml)
- BAR: Secobarbital (300 ng/ml)
- MTD: Methadone (300 ng/ml)
- TCA: Nortriptyline (1000 ng/ml)
- MDMA: 3,4-methylenedioxymethamphetamine (500 ng/ml)
- OXY: Oxycodone (100 ng/ml)

† SAMSHA mandated cut-off concentration

Additionaly the RDDT test can access the validity of the urine sample simultaneously to drug-of-abuse testing. The adulteration pads of the RDDT test are chemical indicator assays that provide visual qualitative results for nitrite, creatinine, pH and oxidizing agents. The RDDT test with Adulteration pads is intended for the professional in vitro diagnostic use only. It is not intended for over-the-counter sale to non-professionals.

The RDDT test provides only preliminary test results for drugs-of-abuse. For a quantitative result or to confirm positive results obtained by the RDDT test, a more specific alternative method must be used. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

**Summary and Explanation**

COC: Cocaine derived from the leaves of the coca plant, is a potent central nervous system stimulant, and has been used as a local anesthetic. Cocaine use induces euphoria, confidence, and a sense of increased energy. These psychological effects are accompanied by increased heart rate, pupil dilation, fever, tremors, and sweating. Cocaine is generally smoked or administered intravenously or orally. Cocaine base can be smoked in the form commonly known as “crack”, which is likely to lead to dependence since the effect is more rapid and heightened. Cocaine is primarily excreted as benzoylecgonine and can generally be detected for 24–60 hours after cocaine use or exposure.2

OMP: Heroin, morphine and codeine are opiates that are derived from the resin of the opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide may both be found in the urine of a person who has taken only heroin. The body also converts codeine to morphine. Thus, the presence of morphine (or morphine metabolite) in the urine indicates heroin, morphine and/or codeine use. Generally, morphine and other opiates can be detected in the urine within 4–6 hours after use and for 3-5 days, depending on urine pH level.2,3

THC: THC use may impair short-term memory and inhibit learning capacity. It may also alter mood and sensory perceptions, cause loss of coordination, induce anxiety, paranoia, hallucinations, depression, confusion, and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur. Long-term THC use may be associated with behavioral disorders. Withdrawal from marijuana use may produce restlessness, insomnia, anorexia, and nausea.

AMP: Amphetamine is chemically related to the human body’s natural catecholamines, epinephrine, and norepinephrine. It has therapeutic applications and is a potent sympathomimetic agent. Amphetamine use in acute higher doses lead to enhanced stimulation of the central nervous system and induces euphoria, alertness, reduced appetite, and a sense of increased energy and power. Generally about 30% of amphetamine is excreted unchanged in 24-hour urine.

PCP: Phencyclidine is an arcylohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, Angel Dust, Crystal Cat, Love Boat Nog or Killer Weed. PCP can produce lethargy, disorientation, and loss of coordination, visual distortion, euphoria, ataxia, and even coma. PCP can be taken orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys. The half-life of phencyclidine is about three days.

BZO: Benzodiazepines are anxiolytics that are most widely prescribed and used as anti-anxiety agents. They are also used as hypnotics, muscle relaxants and anti-convulsants. Some metabolites of benzodiazepines also exhibit pharmacological activities. Use of benzodiazepines can result in drowsiness and confusion; it also potentiates alcohol and other central nervous system depressant. Psychological and physical dependence on benzodiazepines can develop if higher doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by injection. The drug is metabolized in the liver and excreted in the urine as the parent compound or as oxazepam (in the case of chlorodiazepoxide and diazepam). Oxazepam is detectable in the urine for up to 7 days.2,3

BAR: Barbiturates are a class of central nervous system depressants. Phenobarbital has been used as a daytime sedative and extensively as an anticonvulsant. Phenobarbital is an example of long-acting barbiturate derivative while pentobarbital and secobarbital are examples of short-acting barbiturates. Barbiturates, like barbitone use are always smoked or administered intravenously or orally. Cocaine base can be smoked in the form commonly known as “crack”, which is likely to lead to dependence since the effect is more rapid and heightened. Cocaine is primarily excreted as benzoylecgonine and can generally be detected for 24–60 hours after cocaine use or exposure.2

MTD: Methadone is a synthetic analgesic drug that is originally used for the treatment of narcotic addiction. Methadone use induced psychological effects such as analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver. The major route of methadone excretion is in the urine. The effects of methadone last up to 24 hours after use and can be detected in the urine up to 14 days.2,3 The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug use, excretion rate, drug half-life, and the user’s age, weight, activity and diet.

TCA: Tricyclic antidepressants (TCAs) are a type of prescription drugs used for the treatment of depressive disorders. Tricyclic Antidepressants consist of two main chemical classes. The tertiary amines boost serotonin levels and are usually prescribed for insomnia, irritability and overstimulation; these include amitryptiline, imipramine, trimipramine and doxepin. The secondary amines, which include nortryptiline, desipramine and protryptiline, enhance norepinephrine levels and are prescribed for fatigue; withdrawal and inretness.5-6

TCA abuse can result in respiratory depression, convulsions, blood pressure decrease, and coma, and can be taken orally or sometimes by injection. TCAs are excreted in the urine mostly in the form of metabolites for up to ten days. MDMA: 3,4-methylenedioxymethamphetamine (MDMA) is a synthetic drug that is chemically related to the amphetamine family of compounds. MDMA has been available as a street drug since the 1980s, however, since the 1990s its use has increased, particularly among teenagers and young adults. The drug has street names that include "Ecstasy, XTC, Clarity, Essence and Adam". MDMA is typically available in tablet form containing approximately 60-150 milligrams of MDMA. The common method of use is oral ingestion, although the powder form can be snorted and occasionally smoked. MDMA has properties of both stimulants and hallucinogens. The effects of the drug last up to 6 hours after oral ingestion. The adverse effects include elevated blood pressure, increased heart rate, hyperthermia, dehydration, anxiety, paranoia and insomnia. The detection period of MDMA in urine is 1-3 days for single use and up to 5 days for heavy use.1

OXY: Oxycodone is a synthetic analgesic drug administered orally for the relief of pain. The major route of oxycodone excretion is in the urine. The effects of oxycodone last up to 4 hours after use. The length of time following drug use for which a positive result may occur is dependent upon several factors including the frequency and amount of drug use, excretion rate, drug half-life, and the user’s age, weight, activity and diet.

**Adulteration Tests**

The validity of Drugs-of-Abuse (DAU) screening depends on the integrity of the urine samples.4 Contaminated or adulterated samples may cause erroneous results leading to significant consequences. Hence, sample validity testing (SVT) is important to ensure that the samples are intact and unadulterated prior to DAU testing.4,5

Cr: Creatinine is a normal urine constituent. Although the ranges are affected by age, sex, diet, muscle mass and local population distribution, sample with creatinine level lower than 20 mg/dl should be considered diluted. The Department of Transportation (DOT) guideline5 also states that urine specimens...
with creatinine levels less than 20 mg/dl may be indications of dilution or substitution.

Ni: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. Nitrite level above 50 mg/dl is above the clinical level and is considered abnormal.

Ox: Normal urine specimen should be free of any oxidizing (Ox) agents. A positive ‘Ox’ detection in the urine suggests adulteration. Beach and other oxidizing compounds are found in commercially available adulterant products.

pH: The normal urine pH ranges from 4–9. An abnormal ‘pH’ result (below pH 4 or above 10) indicates adulteration with acidic or alkaline adulterants added to the urine.

Test Principle

Urine based screening tests for drugs-of-abuse are available from simple immunoassay tests to complex analytical procedures. Due to speed and sensitivity, immunoassays have become the most widely accepted method for urine-based drugs-of-abuse screening tests. The RDDT family of urine drug screen tests is based on the principle of the highly specific immunochemical reactions between antigens and antibodies. The CLIAwaived, Inc. RDDT test device is based on a competitive immunoassay procedure in which immobilized drug conjugates compete with the drug(s) present in urine for limited antibody binding sites. The test device consists of individual test strips assembled into separate chambers of a plastic insert. On each membrane strip, a drug conjugate is pre-coated at a specific region known as the test region. A colored antibody-collodial gold conjugate is coated onto a pad and placed at one end of the membrane strip. In the test procedure, the CLIAwaived, Inc. RDDT dipcard test device is dipped into a urine sample. This allows the urine into contact with the sample pads of the RDDT test device. The urine then migrates across the membrane by capillary action. If any drug is present in the urine, it competes with the drug conjugate, which is immobilized on the membrane for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibody binding sites and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. The absence of a color band at a specific test region indicates a negative result for that particular test. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the specific test region of the membrane. The presence of a color band at a specific test region indicates a positive result for that particular test.

A control band with a different antigen/antibody reaction is added to the immuno-chromatographic membrane strip at the control region (C) to indicate that the test performed properly. This control band should always appear regardless of the presence of drug or metabolite.

*NOTE: The above illustration depicts 10 drugs-of-abuse tests with the CLIAwaived, Inc. Rapid Dip Drug Test (With Adulteration).

Reagents

Protein conjugate for benzoylecgonine, morphine, methamphetamine, THC, amphetamine, phencyclidine, benzodiazepine, barbiturate, methadone, nortriptyline, MDMA or oxycodone is coated onto the test region of the membrane.

The colored conjugate pad for each strip contains antibodies for benzoylecgonine, morphine, methamphetamine, THC, amphetamine, phencyclidine, benzodiazepine, barbiturate, methadone, tricyclic antidepressant, MDMA or oxycodone. The CLIAwaived, Inc. Rapid Dip Drug Test also contains two test strips with adulteration pads for creatinine (Cr)/Nitrite (Ni) and pH (pH)/Oxidizing Agent (Ox).

Cr: 2.05% creatinine reactive indicator, 97.95% buffer and non-reactive ingredients.
Ni: 0.81% nitrite reactive indicators and 99.19% buffer and non-reactive ingredients.

pH: 0.10% reactive indicator and 99.9% non-reactive ingredients.

Ox: 0.22% indicator and 99.78% non-reactive ingredients.

Test Principle - Adulteration Tests

Cr: The ‘Cr’ pad detect creatinine. The creatinine in the urine sample reacts with a creatinine indicator to form a purple color complex. The color intensity of the tested pad is directly proportional to the concentration of creatinine in the sample.

Ni: The ‘Ni’ pad detect nitrite. This test is based on the reaction of aromatic amine to yield a diazonium salt, which then couples with an indicator to form a color complex ranging from pink to dark red depending on the concentration of nitrite in the sample.

pH: The ‘pH’ pad is based on a double indicator principle that gives a broad range of colors ranging from orange for low pH (<4), to yellow and green (pH4 to 10), to brown for high pH (pH >11).

Ox: The ‘Ox’ pad forms a color complex from blue to brown when an oxidizing agent is present.

Materials Provided

Each CLIAwaived, Inc. Rapid Dip Drug Test Kit contains:

1. Package Insert (directions for use).
2. 1 Color Chart for color matching of adulteration pads.

Each test device is packaged with a desiccant and sealed in a foil pouch.

Warnings and Precautions

FOR IN VITRO DIAGNOSTIC USE ONLY

For professional use only.

The test device should remain in its original sealed pouch until ready for use.

Discard the test device if package is ripped or torn.

Handle all urine specimens as if potentially infectious. Proper handling and disposal methods should be established.

Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample.

Product Storage

The CLIAwaived, Inc. RDDT dipcard test should be stored at room temperature (15°–30°C) until the expiration date on the label. Do not open pouch until ready to perform the assay.

Specimen Collection and Handling

The CLIAwaived, Inc. RDDT tests are formulated for use with urine specimens. Use only freshly voided, untreated urine. Do not centrifuge or add preservatives to urine. Unused samples should be collected in a container that testing may be performed as soon as possible, preferably during the same day. Specimens that have been refrigerated must be brought to room temperature prior to testing. Previously frozen specimens must be thawed, brought to room temperature, and mixed thoroughly prior to testing. Frozen samples are not recommended for adulteration testing.

Note: All materials coming in contact with urine specimens should be handled and disposed of as if potentially infectious. Avoid contact and follow good laboratory practice.

Test Procedure

IMPORTANT: Donor sample (urine specimen) should be brought to room temperature prior to testing. Do not open pouch until ready to perform the assay.

2. Remove the test device from the sealed pouch by tearing at the notch.
3. Detach the bottom cover and dip the sample pads of the RDDT test device straight into the sample for a minimum of 10 seconds. Dip up to, but not beyond the tip of the arrows.
4. Remove the CLIAwaived, Inc. RDDT test from the sample and reattach the bottom cover.
5. Adulteration Tests: Read the results within 1–2 minutes. Do not read test results after 2 minutes. Refer to the color chart provided for color matching and interpretation of results.
6. Drugs-of-Abuse Tests: Once the control band (C) appears (in 5 minutes or less) results are ready to interpret. Read results at 5 minutes.

Interpretation of Results - Drugs-of-Abuse

*Note: The above results are for illustration purposes only, see the explanations on pg. 3 for interpretation of results.
Samples with faint test bands at the test regions indicate a positive result for that particular test. When external control materials are used with a urine specimen. When external controls do not produce a band at the control region, check testing procedures, samples, and/or control materials, and repeat the test using a new device.

Important: Read each test independently. Do not compare color intensity of one test to another. Samples with faint test bands at the test regions should be considered negative. The CLIAwaived, Inc. Rapid Dip Drug Test provides qualitative results for the presence of drug(s) at specified cut-off concentrations. It is recommended that samples with questionable test bands and positive results be confirmed with a more specific quantitative method (Gas Chromatography/Mass Spectrometry).

Interpretation of Results: Adulteration Tests
See enclosed color chart insert. Qualitative results are obtained by visually comparing the color of each test pad with the corresponding color blocks on the chart.

Quality Control
Drugs-of-Abuse Internal Control: The CLIAwaived, Inc. Rapid Dip Drug Test device has built-in internal procedural controls. The appearance of the control bands (C) is considered an internal procedural control. This band should always appear if adequate sample volume is used and the testing procedure is followed. Additionally, the background color should become clear and provide distinct test results. If the control bands (C) do not appear then the test is invalid. The test should be repeated using a new device.

Drugs-of-Abuse External Control: It is recommended that negative and positive urine controls be used to initially test each new lot of product to ensure proper kit performance. The same assay procedure should be followed with external control materials as with a urine specimen. When external controls do not produce the expected results, do not run test specimens. Follow the proper federal, state and local guidelines when running external controls.

Adulteration Tests: Control products are available for the adulteration tests. Contact Branam Medical Corporation for assistance.

Quality control testing at regular intervals is a good laboratory practice and may be required by federal, state or local guidelines. Always check with the appropriate licensing or accrediting bodies to ensure that the quality program employed meets the established standards.

Limitations of Procedure
The assay is designed for use with human urine only. Positive results only indicate the presence of drug/metabolites and do not indicate or measure intoxication. There is a possibility that technical or procedural errors as well other substances in certain food and medication may interfere with the test and cause false results. See Specificity section for the list of substances that will produce either positive results, and Interference section for the list of components that do not interfere with test performance.

If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drugs of abuse and certain food and/or medication. If it is suspected that the sample may have been mislabeled a new specimen should be collected. If it is suspected that the sample may have been tampered, new specimen should be collected.

Performance Characteristics — Precision

**Drugs-of-Abuse:** For each specific drug test, drug-free normal urine was spiked with drug standards to various concentrations (-50%, -25%, +25% and +50%). For each concentration, a total of 30 tests were performed to validate the test performance around the cut-off concentration. The results for each drug test in the RDTT test are summarized below:

**Performance Characteristics — Accuracy**

**Drugs-of-Abuse Tests:** The accuracy of the RDTT test device was evaluated in comparison to the results from GC/MS analysis or other commercially available confirmatory methods. Forty (40) negative urine samples were collected from volunteer donors and tested with each drug test strip. Of the 40 negative urine samples tested, all were found negative by both methods (100% agreement). Additionally, for each drug test a minimum of 40 clinical urine samples previously analyzed by GC/MS method with known concentration(s) of drug(s) were blind labeled and evaluated. The results are summarized below:

<table>
<thead>
<tr>
<th>Drug Test</th>
<th>GC/MS</th>
<th>Neg. (%)</th>
<th>Pos. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocaine</td>
<td>GC/MS</td>
<td>Neg. (%)</td>
<td>Pos. (%)</td>
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<tr>
<td>THC</td>
<td>GC/MS</td>
<td>Neg. (%)</td>
<td>Pos. (%)</td>
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<tr>
<td>MDMA</td>
<td>GC/MS</td>
<td>Neg. (%)</td>
<td>Pos. (%)</td>
</tr>
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</table>

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<th>Neg. (%)</th>
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<tbody>
<tr>
<td>THC 50 ng/ml</td>
<td>Compound</td>
<td>Compounds</td>
<td>Compound</td>
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<tr>
<td>THC 100,000</td>
<td>Cannabinol</td>
<td>11-Hydroxy-9-THC</td>
<td>2,500</td>
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<tr>
<td>THC 100,000</td>
<td>Cannabinol</td>
<td>11-Hydroxy-9-THC</td>
<td>7,000</td>
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<td>THC 100,000</td>
<td>Cannabinol</td>
<td>11-Hydroxy-9-THC</td>
<td>10,500</td>
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**Specificity — Drugs-of-Abuse Tests**

The specificity study for each of the drug test of the RDTT test was evaluated separately by adding structurally related compounds to normal human urine. The results are expressed as the amount in ng/ml of the compound that was observed to produce a positive result.

| THC 50 ng/ml | Compound | Compounds | Compound |
| THC 100,000 | Cannabinol | 11-Hydroxy-9-THC | 2,500 |
| THC 100,000 | Cannabinol | 11-Hydroxy-9-THC | 7,000 |
| THC 100,000 | Cannabinol | 11-Hydroxy-9-THC | 10,500 |

| THC 100,000 | Cannabinol | 11-Hydroxy-9-THC | 2,500 |
| THC 100,000 | Cannabinol | 11-Hydroxy-9-THC | 7,000 |
| THC 100,000 | Cannabinol | 11-Hydroxy-9-THC | 10,500 |
The effects of pH and specific gravity of the specimen on the performance of the drugs-of-abuse tests at cutoff level were tested. Results obtained were acceptable and not affected by any urine samples with pH range of 4.5 to 8.5 and specific gravity range of 1.005 to 1.030.

Expected Results – Adulteration Tests

Cr: Daily creatinine excretion, related to the muscle mass of the human body is usually constant. DOT guidelines state that creatinine levels of less than 20 mg/dl are indicative of dilution.7

Ni: Although nitrite is not a normal component of urine, nitrite levels of up to 3.4 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. Nitrite level above 50mg/dl is above the clinical level and is considered abnormal.

pH: Urine pH may range from 4 to 10. Values below pH 4.0 or above pH 10 are abnormal and indicative of adulteration.

Interferences – Drugs-of-Abuse

Various drugs, drug metabolites, and other contaminants commonly found in urine were evaluated for interferences and cross-reactivity. The following compounds were found not to cross-react with the QuickTox Drug Screen Dipcard test device when tested at concentrations of 100 µg/ml (100,000 ng/ml):

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<table>
<thead>
<tr>
<th>Substance</th>
<th>Assay Notes</th>
</tr>
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<tbody>
<tr>
<td>d-Phenylpropanolamine</td>
<td></td>
</tr>
<tr>
<td>Prednisolone</td>
<td></td>
</tr>
<tr>
<td>Prazepam (except TCA assay)</td>
<td>11-nor-9-TCA-9-Carboxylic Acid (except THC assay)</td>
</tr>
<tr>
<td>Promazine (except TCA assay)</td>
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</tr>
<tr>
<td>Promethazine</td>
<td>11-nor-9-TCA-9-Carboxylic Acid (except THC assay)</td>
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<tr>
<td>d-Propranolol</td>
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<td>Propranolol</td>
<td></td>
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<tr>
<td>Propranolol (except TCA assay)</td>
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<tr>
<td>Propranolol (except TCA assay)</td>
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</tr>
<tr>
<td>Procaine</td>
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<tr>
<td>Quinidine</td>
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<tr>
<td>Quinine</td>
<td></td>
</tr>
<tr>
<td>Ritodrine</td>
<td></td>
</tr>
<tr>
<td>Salicylic acid</td>
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<tr>
<td>Serotonin</td>
<td></td>
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<tr>
<td>Sodium Chloride</td>
<td></td>
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<tr>
<td>Sulfamethazine</td>
<td></td>
</tr>
<tr>
<td>Sulindac</td>
<td></td>
</tr>
<tr>
<td>Temazepam (except TCA assay)</td>
<td></td>
</tr>
<tr>
<td>Tetrahydrocannabinol (except THC assay)</td>
<td></td>
</tr>
<tr>
<td>Tetrahydrocannabinol (except THC assay)</td>
<td>11-nor-9-TCA-9-Carboxylic Acid (except THC assay)</td>
</tr>
<tr>
<td>Triazolam (except BZO assay)</td>
<td></td>
</tr>
<tr>
<td>Tyramine</td>
<td></td>
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<tr>
<td>Uric Acid</td>
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<tr>
<td>Verapamil</td>
<td></td>
</tr>
<tr>
<td>Zomepirac</td>
<td></td>
</tr>
</tbody>
</table>

Bibliography of Suggested Reading

5. Young, D.S. et. al., Clinical Chemistry, 21 (9), 1975.
7. U.S. Dept. of Transportation, Procedures for Transportation Workplace Drug and Alcohol Testing Programs. Federal Register, 1999 Dec.; 64(236); 69076
READ FIRST BEFORE PERFORMING THE CLIAwaived Inc. Rapid Dip Drug Test!

This insert is provided for the adulteration test portion of the CLIAwaived Inc. Rapid Dip Drug Test. Please follow the procedure below.

CLIAwaived Inc. Rapid Dip Drug Test can assess the validity of the urine sample simultaneous to drug-of-abuse testing. The adulteration pads of the CLIAwaived Inc. Rapid Dip Drug Test are chemical indicator assays that detect creatinine, nitrite, pH and oxidizing agents in urine. The CLIAwaived Inc. Rapid Dip Drug Test provides visual qualitative results and is intended for professional in vitro diagnostic use only. It is not intended for over-the-counter sale to non-professionals.

Adulteration Tests

The validity of Drugs-of-Abuse (DAU) screening depends on the integrity of the urine samples. Contaminated or adulterated samples may cause erroneous results leading to significant consequences. Hence, it is important to ensure that the samples are intact and unadulterated prior to DAU testing.

Cr: Creatinine is a normal urine constituent. Although the ranges are affected by age, sex, diet, muscle mass and local population distribution, samples with creatinine level lower than 20 mg/dl should be considered diluted. The Department of Transportation (DOT) guideline also states that urine specimens with creatinine levels less than 20 mg/dl may be indications of dilution or substitution.

Ni: Although nitrite is not a normal component of urine, nitrite levels of up to 10 mg/dl may be found in some urine specimens. Nitrite level above 50 mg/dl is above the clinical level and is considered abnormal.

Ox: Normal urine specimen should be free of any oxidizing (Ox) agents. A positive ‘Ox’ detection in the urine suggests adulteration. Bleach and/or other oxidizing compounds are found in commercially available adulterant products.

pH: The normal urine pH ranges from 4–9. An abnormal ‘pH’ result (below pH 4 or above 10) indicates adulteration with acidic or alkaline adulterants added to the urine.

Reagents & Materials Supplied

- One Color Chart Card

The adulteration test pads, creatinine (Cr)/Nitrite (Ni) and pH (pH)/Oxidizing Agent (Ox) contain the following:

Cr: 2.05% creatinine reactive indicator, 97.95% buffer and non-reactive ingredients.
Ni: 0.81% nitrite reactive indicators and 99.19% buffer and non-reactive ingredients.
pH: 0.10% reactive indicator and 99.9% non-reactive ingredients.
Ox: 0.22% indicator and 99.78% non-reactive ingredients.

Warnings and Precautions

- The adulteration tests are not intended for use in the diagnosis of diseases or illness.
- Do not use this test if you are colorblind.

Testing Procedure

Preparation

1. Allow specimens or controls to warm to room temperature before testing.
2. Do not open test device pouch until ready to perform the test.

Testing

2. Remove the test device from the sealed pouch.
3. Write the urine ID number on the device.
4. Detach the bottom cover and dip the sample pads of the CLIAwaived Inc. Rapid Dip Drug Test test device straight into the sample for a minimum of 10 seconds. **Dip up to, but not beyond the tip of the arrows.**
5. Remove the device from the urine and re-attach the bottom cover. Lay the device on a flat surface.
6. **Read the adulteration test results within 1-2 minutes. Do not read test results after 2 minutes.** Refer to the color chart provided for color matching and interpretation of results.
7. Read the adulteration tests first. Refer to the CLIAwaived Inc. Rapid Dip Drug Test package insert to read and interpret the drugs-of-abuse test results.
Interpretation of Adulteration Tests Results
See enclosed color chart card. Qualitative results are obtained by visually comparing the color of each test pad with the corresponding color blocks on the chart.

Quality Control

Adulteration Tests: Control products are available for the adulteration tests. Contact CLIAwaived Inc. for assistance.

Accuracy (Adulteration tests)
The accuracy of the adulteration tests was verified by an independent laboratory analyzing ten each of the normal and the various adulterated urine specimens. Low creatinine samples were obtained by diluting normal urine with water at a 1:4 ratio. HCl or NaOH was added to urine to obtain acidic or basic specimens. Ultra Bleach, pyridinium chlorochromate (PCC) and sodium nitrite were added to produce the respective adulterated samples.

Results were as follows:

<table>
<thead>
<tr>
<th>Adulterant Test</th>
<th>Normal Samples</th>
<th>Adulterated Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># of Samples</td>
<td>Conc./ Level</td>
</tr>
<tr>
<td>Creatinine</td>
<td>10</td>
<td>50 mg/dl</td>
</tr>
<tr>
<td>pH</td>
<td>10</td>
<td>pH = 7</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>pH = 12</td>
</tr>
<tr>
<td>Nitrite</td>
<td>10</td>
<td>&lt;5 mg/dl</td>
</tr>
<tr>
<td>Oxidizing Agent</td>
<td>10</td>
<td>None</td>
</tr>
</tbody>
</table>

Expected Results

Cr: Daily creatinine excretion, related to the muscle mass of the human body is usually constant. DOT guidelines state that creatinine levels of less than 20 mg/dL are indicative of dilution.7

Ni: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. Nitrite level above 50mg/dl is above the clinical level and is considered abnormal.

pH: Urine pH may range from 4 to 10. Values below pH 4.0 or above pH 10 are abnormal and indicative of adulteration.

Ox: The presence of oxidizing agents in the urine is abnormal and indicative of adulteration.

Bibliography of Suggested Reading
3. Young, D.S. et. al., Clinical Chemistry, 21 (9), 1975.
4. U.S. Dept. of Transportation, Procedures for Transportation Workplace Drug and Alcohol Testing Programs. Federal Register, 1999 Dec.; 64(236); 69076
5. U.S. Dept. of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs. Federal Register, 2001 Aug.; 66(162); 43876

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