The Cliawaived™, Inc. Drugs of Abuse Cup is a rapid, screening test for the qualitative detection of multiple drugs in urine samples. It is indicated for use in conjunction with professional point of care sites. The test is performed by collecting a urine sample, allowing it to stand for 5-10 minutes, and then proceeding with the test.

**HOW TO PERFORM THE TEST?**

1. Remove a test cup from the foil pouch by tearing at the notch. Use it as soon as possible. Instruct the donor to remove the cap.
2. Fill the test cup immediately to the fill line. Do not use test cup if liquid level is below fill line. If the urine is cloudy, mix by shaking the test cup for 30 seconds.
3. Discard after first use. The test cannot be used more than once. Do not use test cup beyond expiration date.
4. Remove the label and read the results. Wait 5 minutes to determine a positive result.
5. If a color band is not visible in the control "C" region or a color band is only visible in the test "T" region, the test is invalid.
6. Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST "T" REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEGATIVE RESULT.

**READ THE RESULTS**

**PRELIMINARY (+)** A new test band is visible in each control region. If no color band appears in the appropriate test "T" region, a preliminary positive result is indicated for the corresponding drug of that specific test line.

**NEGATIVE** A new test band is not visible in each control region and the appropriate test "T" region. It indicates that the concentration of the substance being tested is below the detection level of the test.

**INVALID** If a band is not visible in the control "C" or a control band is only visible in the test "T" region, the test is invalid. Another test should be run and not re-evaluated. If test still provides invalid result, contact the technical support of the kit manufacturer for assistance.

**READING THE RESULTS**

**WARNINGs AND PRECAUTIONs**
- This kit is for external use only.
- Do not use if pouch is perforated or not sealed.
- Do not use after expiration date.

**MATERIALS REQUIRED**
- 25 test devices, one test cup per pouch. Each pouch contains a test cup with integrated test card.
- One (1) Instruction Sheet
- One (1) Adulteration color comparison chart for interpretation of adulteration test results (if equipped)
- 25 Security Seals (if ordered)

**STORAGE AND STABILITY**
- Store at 30-31 °F (4-30 °C) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.
- DO NOT FREEZE.

**PRINCIPLE**

The Cliawaived™ Inc. Drugs of Abuse Cup is a competitive immunoassay that is immune specific to the presence of various drugs in urine. It is a chromatographic test device in which, with urine samples, competition occurs between a labeled drug and an unlabeled drug for the binding sites on a specific drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the device. This prevents the development of a colored test line in the control region of the device. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone can produce symptoms of coma and death. In a methadone overdose, the patient loses consciousness and shows signs of respiratory depression. The time of death is approximately 3 days. This product has been found to be 100% (84.5% - 100%) equivalent by GC/MS analysis. The Cliawaived™ Inc. Drugs of Abuse Cup is a rapid, screening test for the qualitative detection of multiple drugs in urine samples. It is indicated for use in conjunction with professional point of care sites. The test is performed by collecting a urine sample, allowing it to stand for 5-10 minutes, and then proceeding with the test.

**SPECIMEN COLLECTION AND PREPARATION**

The Cliawaived™ Inc. Drugs of Abuse Cup is a rapid, screening test for the qualitative detection of multiple drugs in urine samples. It is indicated for use in conjunction with professional point of care sites. The test is performed by collecting a urine sample, allowing it to stand for 5-10 minutes, and then proceeding with the test.
Precision and Sensitivity

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff - 100%, cutoff - 75%, cutoff - 50%, cutoff - 25%, cutoff + 25%, cutoff + 50%, cutoff + 75% and the cutoff + 100%. All concentrations were confirmed with GC-MS. The study was performed 2 runs/day and lasted 25 days using three different lots of the corresponding Oxytest. Each of the three lots consisted of 25 different concentrations, for a total of 75 determinations per concentration per lot of the corresponding Oxytest. The drugs of abuse tested were:

<table>
<thead>
<tr>
<th>Drug Test</th>
<th>Approximate concentration of test (ng/ml)</th>
<th>Number of determinations per concentration</th>
<th>Mean</th>
<th>S.D.</th>
<th>Neg./Pos. %</th>
</tr>
</thead>
</table>

Adulteration/Specimen Validity Test

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff and were tested with the UScreen tests for the corresponding drugs of abuse.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (ng/ml)</th>
<th>Screening Test</th>
</tr>
</thead>
</table>

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (ng/ml)</th>
<th>Screening Test</th>
</tr>
</thead>
</table>

S.G. Test

The specific gravity test was based on the pKa difference of certain pretreated polyethylene glycol in relation to theionic concentration. The cut-off values change from dark blue to blue-green in urine of low ionic concentration to green and yellow-green in urine of high ionic concentration. A urine specific gravity below 1.003 or above 1.025 is considered abnormal.

OX: Breech or other oxidizing agents react with an oxidant indicator to form a color complex. Observation of a blue-green, medium to dark brown, or orange color indicates adulteration with bleach or other oxidizing agents.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff and were tested with the UScreen tests for the corresponding drugs of abuse. All potential interferences were added at a concentration of 100 ng/ml. None of the urine samples showed any deviation from the expected results.
BIBLIOGRAPHY OF SUGGESTED READING


INDEX OF SYMBOLS

Manufactured For:
Clawaived™, Inc.
San Diego, CA 92121