Alere iCup® Rx Drug Screen User Manual

CLIA CATEGORY: WAIVED
Urine screening test results in 5 minutes.

The Alere iCup® Rx Drugs of Abuse Cup tests for the possible use of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (METH), Methylenedioxymethamphetamine (MDMA), Morphine (MOP/OPI300), Oxycodone (OX), Phencyclidine (PCP), and Tricyclic Antidepressants (TCA).

The Alere® Rx Cup test is a rapid, screening test for the qualitative detection of multiple drugs in human urine. It may be used for pre-employment urine tests.

For healthcare professionals including professionals at point of care sites.

WHAT IS THE Alere® RX DRUGS OF ABUSE CUP?

The Alere iCup® Rx Drugs of Abuse Cup is an immunochromatographic assay for the qualitative determination of the possible use of drugs of abuse in urine. This test is intended for the detection of any one of the drugs of abuse listed above in urine. The Alere® Rx Cup test is to be used for screening only. When preliminary positive results are indicated, a confirmatory method must be used in order to obtain a confirmed analytical result. Gas chromatography-mass spectrometry (GC/MS) is the confirmatory method of choice. However, many toxicology laboratories use other confirmatory methods such as gas chromatography and tandem mass spectrometry (GC-MS). GC/MS is generally accepted as the principle active component in marijuana. When ingested or smoked, marijuana effects are manifested as a state of euphoria, relaxation, and altered sensory perception. The physiological effects are cumulative; the more marijuana consumed, the more pronounced the effects. In normal users, prolonged smoking of marijuana can lead to drowsiness, slurred speech, and dilated pupils.

What is False Positive Test?

A test result that indicates a positive test result when the drug is actually absent. This type of error is produced by the test when a specific cut-off concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test. A false positive test can result from an interferences that are similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and judgment. Depending on the time, frequency, and dose of the use of alcohol, the use of alcohol in combination with other substances can result in toxic effects or death. The use of alcohol can impair the user's ability to drive a vehicle and can lead to pathology similar to that of chronic alcohol use.

METH 

Methamphetamine (MET), Methylenedioxymethamphetamine - ecstasy (MDMA), Morphine 300 (MOP/OPI300), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), What is False Negative Test?

A test result that indicates a negative test result when the drug is actually present. This type of error is produced by the test when a specific cut-off concentration of the corresponding drug of that specific test zone is present or above the detection limit of the test. A false negative test can result from the development of a distinct colored band in the test region, indicating a preliminary positive result. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

Reading the results

The Alere iCup® Rx Drugs of Abuse Cup is a competitive immunoassay that is used to screen for the presence of certain drugs of abuse in urine. The Alere iCup® Rx Drugs of Abuse Cup includes all necessary reagents for the qualitative screening of the possible use of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (METH), Methylenedioxymethamphetamine (MDMA), Morphine (MOP/OPI300), Oxycodone (OX), Phencyclidine (PCP), and Tricyclic Antidepressants (TCA). The Alere iCup® Rx Drugs of Abuse Cup is a competitive immunoassay that is used to screen for the possible use of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (METH), Methylenedioxymethamphetamine (MDMA), Morphine (MOP/OPI300), Oxycodone (OX), Phencyclidine (PCP), and Tricyclic Antidepressants (TCA) in human urine.

Background information

4. Remove the label and read the results. Wait 5 minutes to determine a positive result.

WHAT IS THE CUTOFF VALUE AND APPROXIMATE DETECTION TIME?

WHEN TO COLLECT URINE FOR THE TEST?

HOW TO PERFORM THE TEST?

Test must be performed at room temperature, 15-30°C (60-86°F).

WHEN TO COLLECT URINE FOR THE TEST?

WHAT IS THE CUTOFF VALUE AND APPROXIMATE DETECTION TIME?

If you have any question regarding to the use of this product, please contact 1-800-340-4029.

HOW TO PERFORM THE TEST?

Test must be performed at room temperature, 15-30°C (60-86°F).

1. Unpack and shake the test strip so that all reagents are on a flat surface.

2. Immediately read the temperature to verify that the urine temperature is within the acceptable range 32-38ºC (90-100ºF).

3. Place the urine sample into the Cup and allow it to fill to the top of the Cup. Do not overfill.

4. Remove the label and read the results. Wait 5 minutes to determine a positive result.

WARNINGs AND PRECAUTIONS

Allergies, adverse effects of 3,4-methylenedioxymethamphetamine use include jaw clenching, teeth grinding, dilated pupils, perspiring, anxiety, blurred vision, vomiting, and increased blood pressure and heart rate. Overdose of 3,4-methylenedioxymethamphetamine may cause heart failure or extreme heart failure. 3,4-methylenedioxymethamphetamine overdose may be treated similarly to other sympathomimetic amines, such as cocaine. Phencyclidine (PCP) is a common lycol and cocaine, and is metabolized by demethylase to noroxycodone and oxymorphone. Codeine also partially metabolizes to morphine and morphine glucuronide. Thus, the presence of PCP, methamphetamine, or cocaine may result in false positive test results. The presence of PCP, methamphetamine, or cocaine may result in false positive test results.

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WHAT IS THE CUTOFF VALUE AND APPROXIMATE DETECTION TIME?

WHAT IS THE Alere® RX DRUGS OF ABUSE CUP?

The Alere iCup® Rx Drugs of Abuse Cup is a competitive immunoassay that is used to screen for the possible use of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (METH), Methylenedioxymethamphetamine (MDMA), Morphine (MOP/OPI300), Oxycodone (OX), Phencyclidine (PCP), and Tricyclic Antidepressants (TCA).

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**Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), PRINCIPLE**

Drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When the drug levels within the participating in the study of the corresponding Alere iCup using three different lots of the corresponding Alere iCup B are quantified in 0-100 ng/mL range (0.000-0.003 mg/dL) range. The following substrates have been produced positive results with the test when tested at levels equal or greater than the concentrations listed below.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Minimum Positive Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Cocaine</td>
<td>30 ng/mL</td>
</tr>
<tr>
<td>Marijuana</td>
<td>2 ng/mL</td>
</tr>
<tr>
<td>Methadone</td>
<td>100 ng/mL</td>
</tr>
</tbody>
</table>

**PRINCIPLE**

The presence of any chromat in urine is indicative of substance as chromat is not a normal constituent of urine.

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**Interfering substances**

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added directly to urine with drug concentration 25% above the cutoff, and urine with drug concentration 25% above the cutoff and were tested with the Alere iCup Rx Drugs of Abuse Cup. All positive interference were defined as a concentration of 10 ng/mL. None of the urine samples showed any deviation from the expected results.

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**BIBLIOGRAPHY OF SUGGESTED READINGS**


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**Adulteration/Specimen Validity Test**

Gr. Creatinine exists with a creatinine indicator in an edible medium to form a purple/dark brown complex or creatinine in the urine is present at the normal level. The color intensity is directly proportional to the concentration of creatinine. A urine sample with creatinine concentration of less than 25 ng/mL produces a very light, or no color change, which indicates adulteration in the form of creatinine solution.

S.G. The specific gravity test is based on the ratio change of certain pretreated body fluids to the final substance. Two positive results will change from light yellow to dark yellow in a urine sample concentrate of green and yellowish green to urine of higher saccharic concentration. A urine sample generally below 1.003 or above 1.025 is considered adulteration.

GL. Bleach or other oxidizing agents react with an existing 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.

pH. Normal urine pH ranges from 4.5 to 8.5. Values below pH 4.5 or above pH 8.5 are indicative of adulteration.

GL. Glutathione is not a natural component of human urine and should not be present in normal urine. The presence of glutathione in the urine sample indicates the possibility of adulteration. However, false positive may result when storage bodies are present in urine. False positives may appear when a person is in ketosis, starvation or other metabolic abnormalities.

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**INDEX OF SYMBOLS**

- Keep away from sunlight
- Store between 4-40°C (40°F)
- Keep dry
- Do not let in contact with the skin