Professional Cup Urine Drug Controls: Negative, Positive

Intended Use
The Alere™ Professional Cup Urine Drug Controls are designed to monitor and validate the performance of drugs of abuse detection methods at levels established by SAMHSA, CAP/AACD, and many state programs. The Alere™ Professional Cup Urine Drug Controls are compatible with all quantitative and qualitative drug detection procedures which are sufficiently sensitive to detect the control constituents. They should be treated as any "unknown" specimen while following the specific protocol of the assay being used. This product is intended to be used by health care professionals as an integral part of a quality control system.

Summary and Explanation
The DEA exempt Alere™ Professional Cup Urine Drug Control product line of controls is manufactured using a human based matrix that has been stabilized to ensure that the product will be viable until the date of expiration. Positive controls are spiked with reference drug standards and/or appropriate metabolites that have been obtained from ISO certified manufacturers. Standards are certified by the manufacturers to be at least 98% minimum purity. Specific gravity, pH, and creatinine fall within the limits of normal human urine.

Description
Each bottle contains stabilized human based urine. Positive control urines have been spiked with authentic reference drug standards and/or appropriate metabolites that have been obtained from ISO certified manufacturers. Standards are certified by the manufacturers to be at least 98% minimum purity. Specific gravity, pH, and creatinine fall within the limits of normal human urine.

Storage & Stability
Please refer to Limitations for detailed instructions.

Unopened:
A. The controls are stable until the expiration date when stored at -20 to -10°C and protected from light.
B. The controls are stable until the expiration date when stored at 2 to 8°C. However, no stability claims can be made for Oxazepam as it may deteriorate over time when stored refrigerated.

After Opening:
(Controls can be aliquoted and frozen)
A. The controls are stable for six months or until the expiration date, whichever comes first, when stored at -20 to -10°C.
B. The controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2 to 8°C.
C. Thaw controls as needed; allow controls to come to room temperature followed by gentle swirling before use.

Procedure
Allow controls to come to room temperature followed by gentle swirling or inversion before use. DO NOT SHAKE. Pipette an appropriate aliquot of Alere™ Professional Cup Urine Drug Control sample as required by the drugs of abuse test device or screening method.

Expected Results
The positive control must test positive on the drugs of abuse test device or screening method. The negative control must test negative.

Precautions
For In Vitro Diagnostic Use Only.
Please read the entire package insert before using the Alere™ Professional Cup Urine Drug Controls. Please use the same safety precautions you would use for processing any "unknown" urine sample containing potentially infectious biological material. Protect product from exposure to direct sunlight. Contains sodium azide: To prevent formation of explosive metal azides dispose of waste by flushing with copious amounts of water or according to local governing regulations.

Limitations of Procedure
This product is not meant to be used as a quality control system. It is included as an integral part of the drug test procedure. The negative control must test negative on the drugs of abuse test device or screening method. The positive control must test positive on the drugs of abuse test device or screening method.

Alere™ Professional Cup Urine Drug Controls, Target Values (ng/mL)

<table>
<thead>
<tr>
<th>Drug Assay Class</th>
<th>Drug</th>
<th>Negative Control</th>
<th>Positive Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>d-Amphetamine</td>
<td>0</td>
<td>3000</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>Secobarbital</td>
<td>0</td>
<td>900</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Buprenorphine Glucuronide</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Oxazepam</td>
<td>0</td>
<td>900</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Benzoylglucuronine</td>
<td>0</td>
<td>900</td>
</tr>
<tr>
<td>MDMA</td>
<td>3,4-Methylenedioxyamphetamine</td>
<td>0</td>
<td>1500</td>
</tr>
<tr>
<td>Methadone</td>
<td>Methadone</td>
<td>0</td>
<td>900</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>d-Methamphetamine</td>
<td>0</td>
<td>3000</td>
</tr>
<tr>
<td>Opiates</td>
<td>Morphine (High Opiate)</td>
<td>0</td>
<td>600</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Oxycodone</td>
<td>0</td>
<td>300</td>
</tr>
<tr>
<td>PCP</td>
<td>Phencyclidine (PCP)</td>
<td>0</td>
<td>75</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>d-Propoxyphene</td>
<td>0</td>
<td>900</td>
</tr>
<tr>
<td>THC</td>
<td>Delta-9-THC-COOH</td>
<td>0</td>
<td>150</td>
</tr>
<tr>
<td>Tricyclic Antidepressants</td>
<td>Nortriptyline</td>
<td>0</td>
<td>3000</td>
</tr>
</tbody>
</table>

References:

Technical Assistance:
Alere: 800.340.4029
Alere Toxicology Services-Products Division: 800.340.4029

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LOW VOLUME CONTROL PROCEDURE

1. Place the Alere™ Professional Cup Urine Control kit on its side, open flap and slide the white low volume procedure stand out of the box.

2. Empty contents of the positive or negative control into the cup, and then secure the lid on the cup to prepare for reading the results.

3. Place the cup onto the white volume procedure stand with bottom toward the bottom arrows. Line up front of cup to the back of the front wall. Wait 5 minutes to read results.