DRI® Drugs of Abuse Urine Calibrators and Controls

**Intended Use**

The DRI® Drugs of Abuse Urine Calibrators and Controls are intended for the calibration and validation of drugs of the DRI Amphetamine, Cocaine, Opiate and Phencyclidine Assays.

**Description of the Multi-Drug Calibrators and Controls**

The DRI Drugs of Abuse Urine Calibrators and Controls are liquid and ready-to-use. They are prepared by spiking negative human urine with known quantities of d-methamphetamine, benzoylecgonine (major metabolite of cocaine), morphine and phencyclidine. The Low Calibrator is used as a qualitative cutoff reference for distinguishing between “positive” and “negative” samples. When a rough estimate of drug concentration is required, a calibration curve can be established with the Negative, Low and High Calibrators. The High Calibrator also can be diluted with the negative urine to prepare calibrators with desired concentrations. The concentrations (as validated by GC/MS technique) for each drug analyte in these calibrators and controls are outlined in Table 1.

**Table 1. Drug Concentrations in Urine Calibrators & Controls**

<table>
<thead>
<tr>
<th>Drug Analyte</th>
<th>Low Calibrator</th>
<th>High Calibrator</th>
<th>Level 1 Control</th>
<th>Level 2 Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>d-Methamphetamine</td>
<td>1000</td>
<td>2000</td>
<td>750</td>
<td>1250</td>
</tr>
<tr>
<td>Benzoylcegonine</td>
<td>300</td>
<td>1000</td>
<td>225</td>
<td>375</td>
</tr>
<tr>
<td>Morphine</td>
<td>300</td>
<td>1000</td>
<td>225</td>
<td>375</td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>25</td>
<td>100</td>
<td>20</td>
<td>35</td>
</tr>
</tbody>
</table>

**Precautions and warnings**

Drugs of Abuse Urine Calibrators and Controls are for in vitro diagnostic use only. They are harmful if swallowed.

**DANGER:** Calibrators contain ≤0.09% sodium azide and ≤0.3% bovine serum albumin (BSA). Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

The calibrators and controls are prepared from non-sterile human urine. The human urine used in the preparation of calibrators and controls were tested by an FDA approved method and found to be non-reactive for hepatitis B surface antigen and HIV antibody. Because no test method can offer complete assurance that it will not transmit any infectious agents. Handle the calibrators and controls as if they were potentially infectious.

Do not use the calibrators and controls beyond their expiration dates.

**Preparation and Storage**

The Urine Calibrators and Controls are ready-to-use. Store them at 2-8°C when not in use.

**Assay Procedure**

For procedures, refer to the instrument parameter sheet for each specific drug immunoassay.

**Results**

The Low (cutoff) Urine Calibrator* is used as a reference for distinguishing “positive” from “negative” samples. A sample that gives a change in absorbance (ΔA) value equal to or greater than the Low (cutoff) Calibrator is considered positive. A sample that gives a change in absorbance (ΔA) value lower than the Low (cutoff) Calibrator is considered negative. The controls should be used in parallel to validate assay performance. Control results should be within established ranges, as determined by your laboratory.

When a rough estimate of the drug concentration is required, a calibration curve can be established with the Negative, Low and High Calibrators. The concentration of the sample can be obtained by quantitating off the standard curve. When the sample concentration is greater than the highest calibration, it may be diluted and retested.

**Limitations**

Drugs of Abuse Urine Calibrators and Controls are designed for use only with the DRI Amphetamine, Cocaine, Opiate and Phencyclidine Assays.

**Quality Control**

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.