**DRI® Cotinine Calibrators and Controls**

**Intended Use**
The DRI® Cotinine Calibrators are intended for the calibration of the DRI Cotinine Assay. The DRI Cotinine Controls are intended for the validation of DRI Cotinine Assay calibration. These calibrators and controls should be used for in vitro diagnostic use only for the detection of cotinine in human urine.

**Description of the DRI Cotinine Calibrators and Controls**
The DRI Cotinine Calibrators and Controls are liquid and ready-to-use. They are prepared by spiking negative human urine with a known quantity of cotinine, a metabolite of nicotine. The DRI Cotinine 500 ng/mL Calibrator can be used as a qualitative cutoff reference for distinguishing “positive” from “negative” samples. A rough estimate of drug concentration in the samples can be obtained by running a standard curve with the appropriate calibrators and by quantitating samples off the standard curve.

The following table lists the drug concentration in the DRI Cotinine Calibrator kit and Controls:

<table>
<thead>
<tr>
<th>Calibrator Concentration (ng/mL)</th>
<th>Control Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative 0</td>
<td>Low 300</td>
</tr>
<tr>
<td>100 ng/mL 100</td>
<td>High 700</td>
</tr>
<tr>
<td>250 ng/mL 250</td>
<td></td>
</tr>
<tr>
<td>500 ng/mL 500</td>
<td></td>
</tr>
<tr>
<td>1000 ng/mL 1000</td>
<td></td>
</tr>
<tr>
<td>2000 ng/mL 2000</td>
<td></td>
</tr>
</tbody>
</table>

*DRI Cotinine Controls (Low and High) are sold separately.

**Precautions and warnings**
The DRI Cotinine Calibrators and Controls are for in vitro diagnostic use only. They are harmful if swallowed.

**DANGER:** DRI Cotinine Calibrators and Controls contain ≤0.3% bovine serum albumin (BSA).

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 contain ≤0.09% sodium azide. 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.

The calibrators and controls are prepared from non-sterile human urine. **Handle the calibrators and controls as if they were potentially infectious.**

Do not use the calibrators or controls beyond their expiration dates printed on their respective labels.

**Calibrators and Controls Preparation and Storage**
The DRI Cotinine Calibrators and Controls are ready to use. When stored at 2-8°C, they are stable until the expiration date indicated on the label.

**Assay Procedure**
For further instructions, refer to the DRI Cotinine Assay package insert and the appropriate analyzer-specific protocol sheet.

**Quality Control and Calibration**
Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Each laboratory must establish its own acceptable ranges. If results fall outside of the established range, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

**Qualitative analysis**
For qualitative analysis of samples, use the 500 ng/mL calibrator as a cutoff level. The DRI Cotinine Calibrator, which contains 500 ng/mL cotinine, is used as a cutoff reference for distinguishing “positive” and “negative” samples.

**Semiquantitative analysis**
For semiquantitative analysis, use all calibrators.

**Results and Expected Values**

**Semiquantitative Results**
A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve. When the estimated sample concentration is greater than the highest calibrator, the sample can be diluted in Negative Calibrator and retested.

**Qualitative Results**
A sample that exhibits a change in absorbance (∆A) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (∆A) value lower than the value obtained with the cutoff calibrator is considered negative.

**Limitations**
The DRI Cotinine Calibrators and Controls are designed for use with the DRI Cotinine Assay for the detection of cotinine in human urine only.

**Glossary:**
http://www.thermofisher.com/symbols-glossary

**For insert updates go to:**
www.thermoscientific.com/diagnostics

Other countries:
Please contact your local representative.

© 2017 Thermo Fisher Scientific Inc. All rights reserved.

Other countries:
Please contact your local representative.