**Intended Use**
The DRI® THC (11-nor-Δ²-THC-9-carboxylic acid) Urine Calibrators and Controls are intended for in vitro diagnostic use for the calibration and validation of the DRI Cannabinoid (THC) assay which detects THC in human urine.

**Description of the Calibrators and Controls**
The THC Urine Calibrators and Controls are human urine-based and ready-to-use. They are prepared by spiking negative urine with known quantities of 11-nor-Δ²-THC-9-carboxylic acid, which is the major metabolite of Δ²-THC. The THC concentration is validated with a Gas Chromatography/Mass Spectrometry (GC/MS) method.

**Precautions and warnings**
The THC Urine Calibrators and Controls are harmful if swallowed.

**ASSAY**
The urine calibrators and controls 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 reactions.
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 becomes 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. Handle them as if they were potentially infectious.

Do not use the calibrators/controls beyond their expiration date.

**Calibrators and Controls Preparation and Storage**
The THC Urine Calibrators and Controls are ready-to-use. No preparation is required. The calibrators and controls should be stored refrigerated at 2-8°C. They are stable until the expiration date indicated on the label.

**Assay Procedure**
For procedures and further details, refer to the DRI Cannabinoid Assay package insert and application sheet instructions for each analyzer.

**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 control 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.

**Results**
THC urine calibrators, 20 ng/mL, 50 ng/mL and 100 ng/mL, have been used as a cutoff reference for distinguishing "positive" from "negative" samples in pre-employment or SAMHSA initial testing for screening marijuana metabolites in urine. A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the chosen cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the chosen cutoff calibrator is considered negative.

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

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration.

**Limitations**
The THC Urine Calibrators and Controls are designed for use with the DRI Cannabinoid (THC) Assay for the detection of THC in human urine only.

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