Intended Use
The Thermo Scientific CEDIA THC OFT Calibrators are intended for use in the calibration of 1-∆9 THC when used with the CEDIA® Cannabinoids OFT Assay for human oral fluid samples collected with the Oral-Eze® Oral Fluid Collection System. This in vitro diagnostic device is intended for clinical laboratory use only.

Description of CEDIA THC OFT Calibrators
The CEDIA THC OFT Calibrators are liquid ready-to-use. They are prepared by spiking known quantities of l-isomer 1-∆9 THC into buffer matrix. The 1.0 ng/mL cutoff calibrator is used as a qualitative cutoff reference for distinguishing “positive” from “negative” samples. Drug concentrations in the CEDIA THC OFT Calibrators are as follows:

<table>
<thead>
<tr>
<th>Calibrator</th>
<th>Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Calibrator</td>
<td>0</td>
</tr>
<tr>
<td>Cutoff Calibrator</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Each calibrator is sold separately and may be used with any reagent lot.

Precautions and Warning
The CEDIA THC OFT Calibrators are for in vitro diagnostic use only. They are harmful if swallowed.

WARNING: The calibrators contain ≤0.09% sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up. Handle the calibrators as if they were potentially infectious. Do not use the calibrators beyond their expiration dates printed on their respective labels.

Storage
The calibrators should be stored at -20°C when not in use. They are stable until the expiration date indicated on the box label as long as they remain unopened. Once opened they are stable for 50 days from the date of opening.

Instructions for use
The CEDIA THC OFT Calibrators are liquid ready-to-use. Mix the contents of the vial before each use by gentle inversion. Remove the cap and dispense. After each use, tightly close each cap and return to refrigerated storage (2-8°C).

Assay Procedure
For instructions, refer to the instrument specific application sheet for the CEDIA Cannabinoids OFT Assay.

Interpretation of Results
The 1.0 ng/mL calibrator is used as a cutoff reference for distinguishing “positive” from “negative” samples. A sample that exhibits a change in absorbance value (∆A) equal to or greater than that obtained with cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value (∆A) lower than that obtained with the cutoff calibrator is considered negative. The controls should be used in parallel to validate the assay. The results of the controls should be within the range established by each laboratory.

Limitations
The CEDIA THC OFT Calibrators designed for use with the CEDIA Cannabinoids OFT Assay for the detection of cannabinoids in human oral fluid. All quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements.

Bibliography
1. CEDIA Cannabinoids OFT Assay Package Insert.

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538
USA:
1-800-232-3342

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

The MGC 240 is distributed by Thermo Fisher Scientific. CEDIA is a registered trademark of Roche Diagnostics.