

CEDIA® THC OFT Calibrators

Thermo
SCIENTIFIC

IVD For In Vitro Diagnostic Use Only

REF 10014922 CEDIA® THC OFT Negative Calibrator (10 mL)
10014923 CEDIA® THC OFT Cutoff Calibrator (5 mL)

Intended Use

The Thermo Scientific CEDIA THC OFT Calibrators are intended for use in the calibration of *Δ⁹* 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 *Δ⁹* 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:

Calibrator	Concentration (ng/mL)
Negative Calibrator	0
Cutoff Calibrator	1.0

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 (ΔA) equal to or greater than that obtained with cutoff calibrator is considered positive. A sample that exhibits a change in absorbance value (ΔA) 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.

LOT

Lot Number / Número de Lote / Chargennummer / Numéro de lot / Numero di lotto

IVD

"Use By" date / Fecha de caducidad / Haltbarkeitsdatum / Date limite d'utilisation optimale / "Utilizzare entro"

REF

Refrigerated temperature limitation / Limitación de la temperatura de refrigeración / Kühltoleranzgrenze / Limites de température pour un colis réfrigéré / Limite delle temperature di raffreddamento

EC REP

Catalog Number / Número De Catálogo / Katalognummer / Catalogue N° / Numero di catalogo

IVD

Manufacturer / Fabricante / Hersteller / Fabricant / Produttore

REF

Caution / Precaución / Vorsicht / Attention / Attenzione

EC REP

Consult instructions for use / Consultar las instrucciones de uso / Gebrauchsanweisung beachten / Se référer au mode d'emploi / Consultare le istruzioni per l'uso

IVD

Authorized Representative / Representante autorizado / Vertragshändler / Mandataire / Rappresentante autorizzato

CALIBRATOR

For In Vitro Diagnostic Use / Para uso en diagnóstico in vitro / In-vitro-Diagnostikum / Diagnostics in vitro / Per uso diagnostico in vitro

Calibrator / Kalibrator / Calibrateur / Calibratore / Calibrador



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