

CEDIA® Multi-Drug OFT Cutoff Calibrator Set B

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This test kit is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

REF 10022355 CEDIA® Multi-Drug OFT Cutoff Calibrator Set B (10 mL)

Intended Use

The Thermo Scientific CEDIA Multi-Drug OFT Cutoff Calibrator Set B is intended for use in the calibration of secobarbital, nordiazepam, methadone and oxycodone in human oral fluid when used with the CEDIA Barbiturates, Benzodiazepines, Methadone, and Oxycodone OFT Assays on clinical chemistry analyzers.

Description of CEDIA Multi-Drug OFT Cutoff Calibrator Set B

The CEDIA Multi-Drug OFT Cutoff Calibrator Set B is liquid ready-to-use. It is prepared by spiking known quantities of secobarbital, nordiazepam, methadone, and oxycodone into buffer matrix. The cutoff calibrator is used as a qualitative cutoff reference for distinguishing "positive" from "negative" samples. The concentration for each drug in the cutoff calibrator is listed in table below. Concentration for the cutoff calibrator is confirmed by LC-MS/MS methodology.

Compound	Cutoff Calibrator (ng/mL)
Secobarbital	20
Nordiazepam	1
Methadone	5
Oxycodone	10

Cutoff Calibrator is sold separately and may be used with any reagent lot.

Precautions and Warning

The CEDIA Multi-Drug OFT Cutoff Calibrator Set B is for Criminal Justice and Forensic use only. It is harmful if swallowed. Do not use the calibrator beyond its expiration dates printed on its labels.

DANGER: The calibrator contains ≤0.22% Bovine Serum Albumin (BSA).

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 calibrator contains ≤0.09% Sodium azide. Avoid contact with skin and mucous membranes. Refer to SDS for additional precautions, handling instructions, and accidental exposure treatment.

In the case of accidental spill, clean and dispose of material according to your laboratory's SOP, local, and state regulations.

In the case of damaged packaging on arrival, contact your technical support representative (refer to contact number listed in this Package Insert).

Storage

 The calibrator should be stored refrigerated at 2° to 8°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 60 days from the date of opening.

Instruction For Use

The CEDIA Multi-Drug OFT Cutoff Calibrator Set B is 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 OFT Assays for Barbiturates, Benzodiazepines, Methadone, and Oxycodone.

Interpretation of Results

The cutoff 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 the 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 Multi-Drug OFT Cutoff Calibrator Set B is designed for use with the CEDIA OFT Assays to detect secobarbital, nordiazepam, methadone, and oxycodone in human oral fluid.

Bibliography

1. CEDIA Barbiturates OFT Assay Package Insert
2. CEDIA Benzodiazepines OFT Assay Package Insert
3. CEDIA Methadone OFT Assay Package Insert
4. CEDIA Oxycodone OFT Assay Package Insert

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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