

CEDIA® Antibiotic TDM Multi-Cal

IVD For In Vitro Diagnostic Use

Rx Only

REF 100017 Antibiotic TDM Multi-Cal Low (2 x 7.5 mL)
Antibiotic TDM Multi-Cal High (2 x 5.0 mL)

Intended Use

The CEDIA® Antibiotic TDM Multi-Cals are used to calibrate the CEDIA assays for Tobramycin and Gentamicin in human serum and plasma.

Each calibrator set is sold separately and may be used with any reagent lot. The ready-for-use calibrators contain buffer salts, ≤0.09% sodium azide and the following substances. (Refer to the assignment addendum included in the kit for the actual calibrator values):

Substance	Low	High
Bovine Serum Albumin	0.45 g	0.3 g
Tobramycin		0.06 mg
Gentamicin		0.06 mg

⚠ Precautions and Warnings

DANGER: CEDIA Antibiotic TDM Multi-Cals contain ≤6.0% 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 reagents 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.

WARNING. This product contains chemical(s) known to the state of California to cause cancer and/or birth defects or other reproductive harm.

Storage and Stability¹

Store calibrators at 2-8°C. **DO NOT FREEZE.**

Stability prior to opening the bottle:
Up to the printed expiration date.

Stability after opening the bottle:
60 days or until the printed expiration date, whichever comes first.

Procedure

Materials provided:

CEDIA Antibiotic TDM Multi-Cals

Additional materials required (but not provided):

CEDIA reagent kits for the assay of Tobramycin and Gentamicin.

Instructions for use:

The calibrators are liquid and do not require reconstitution. Mix the contents of the vial before each use by gently inverting the vial 2-3 times.

Record the date on which the calibrator was opened on the vial label.

Remove the cap and dispense the required quantity of the calibrator into a sample cup as specified in the appropriate CEDIA assay application sheet.

Avoid cross-contamination of calibrator levels by matching colored calibrator caps to the appropriately colored dropper tips.

Results

The CEDIA Antibiotic TDM Multi-Cals are used to determine drug concentrations. Refer to the appropriate CEDIA Assay package insert or application sheet for specific information.

Limitations

The CEDIA Antibiotic TDM Multi-Cals are intended for use solely as specified. Further information is given in the CEDIA package inserts and instrument specific application sheets.

Quality Control

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

References

1. Data on file at Microgenics Corporation, a part of Thermo Fisher Scientific.

Glossary:

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



Microgenics Corporation
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US Customer and
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1-800-232-3342



EC REP

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

Other countries:

Please contact your local Thermo Fisher Scientific representative.

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