

**IVD** For In Vitro Diagnostic Use

**Rx Only**

**REF** 100007 Core TDM Multi-Cal Low (2 x 7.5 mL)  
Core TDM Multi-Cal High (2 x 5.0 mL)

## Intended Use

The CEDIA® Core TDM Multi-Cals are used to calibrate the CEDIA assays for Carbamazepine, Phenobarbital, Phenytoin, Theophylline, and Valproic acid in human serum and plasma.

Each calibrator set is sold separately and may be used with any reagent lot. The ready-for-use solutions contain buffer salts, <0.15% 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
Carbamazepine	*	0.1 mg
Phenobarbital	*	0.4 mg
Phenytoin	-	0.2 mg
Theophyllin	*	0.2 mg
Valproic Acid	*	0.75 mg

\* Trace Amount

## Precautions and Warnings

**CAUTION. DANGER:** The reagents contain <0.15% sodium azide and ≤5.89% 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 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.

**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 Stability<sup>1</sup>

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 Core TDM Multi-Cals

### Additional materials required (but not provided):

CEDIA reagent kits for the assay of Carbamazepine, Phenobarbital, Phenytoin, Theophylline or Valproic acid.

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

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 Core 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 Core 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  
Technical Support:  
1-800-232-3342



**EC REP**

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For insert updates go to:  
[www.thermofisher.com/diagnostics](http://www.thermofisher.com/diagnostics)

## Other countries:

Please contact your local Thermo Fisher Scientific representative.

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