

CEDIA® Cyclosporine PLUS Calibrator

thermo
scientific

IVD For In Vitro Diagnostic Use

Rx Only

REF 100012 Cyclosporine High Range Cal A (2 x 4.0 mL)
Cyclosporine High Range Cal B (2 x 4.0 mL)

Intended Use

The CEDIA® Cyclosporine PLUS High Range calibrators are used to calibrate the CEDIA Cyclosporine PLUS High Range Assay in human whole blood. Each calibrator set is sold separately and may be used with any reagent lot. The calibrators contain buffer salts, < 0.13% sodium azide and the following substances.

Cat. No. 100012	BSA (g)	Cyclosporine (µg)
High Range A	0.72	1.8
High Range B	0.72	8.0

Refer to the assignment addendum included in the kit for the actual calibrator values.

⚠ Precautions and Warnings

DANGER: CEDIA calibrators contain ≤18% bovine serum albumin (BSA).

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

EUH032 - Contact with acids liberates very toxic gas.

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 calibrators contain less than 0.13% sodium azide. Avoid contact with skin and mucus 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 calibrators, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

Storage and Stability

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

For stability of the unopened calibrators refer to the box or bottle labels for the expiration date.

For stability **after** opening the bottle 60 days or until the printed expiration date, whichever comes first.

Procedure

Material provided:

CEDIA Cyclosporine PLUS High Range Calibrators.

Additional material required (but not provided):

CEDIA Cyclosporine PLUS Reagent Kit

CEDIA Cyclosporine PLUS High Range Controls 4 and 5

Calibration Preparation

1. Mix the calibrators gently but thoroughly before use.
2. Add exactly 100 µL of the calibrator to a sample cup.
3. Using a repeater pipette, add exactly 400 µL of CEDIA Cyclosporine Plus Lysing Reagent to each sample cup.
4. Vortex each sample cup for 2-5 seconds.
5. Place the calibrator cup on the instrument and assay.

The calibrators are stable for 1.5 hour at 15-25°C.

Assay

The CEDIA Cyclosporine PLUS Calibrators are used to determine Cyclosporine concentrations. Refer to the Cyclosporine PLUS reagent kit package insert for specific information.

Quality Control

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

Glossary:

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



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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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