IVD For In Vitro Diagnostic Use

Rx Only

REF 100277

Intended Use

The CEDIA® Mycophenolic Acid (MPA) Calibrators are intended for use in the calibration of the CEDIA MPA Assay.

Calibrator Constituents

The CEDIA MPA Calibrators are prepared in buffer matrix, with pure chemicals, stabilizers, and preservatives. The calibrators are liquid ready-to-use form. They contain the following targeted concentrations of MPA:

Low Calibrator	0 µg/mL
High Calibrator	10 µg/mL

Refer to the value assignment card included in the kit for the actual calibrator values, to be programmed under instrument parameters. The values are derived from replicated analysis, confirmed by LC-MS/MS methodology, and are lot specific.

Calibrators are formulated using Mycophenolic Acid (CAS No. 24280-93-1) and are traceable to a gravimetric method.

Materials provided:

 CALIBRATOR
 CEDIA MPA Low Calibrator
 2 x 5.0 mL

 CALIBRATOR
 CEDIA MPA High Calibrator
 2 x 5.0 mL

Additional materials required (but not provided):

REF	Kit Description
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100278 MAS Mycophenolic Acid Control 1

- 100279 MAS Mycophenolic Acid Control 2
- 100280 MAS Mycophenolic Acid Control 3

Storage and Stability

The calibrators are stable until the expiration date printed on the label when stored at 2-8°C.

Procedure

Thoroughly mix the contents of the vial before each use by gently inverting several times. Open the cap and drop 3 to 4 drops of the liquid calibrator (~150 μ L) into a clean instrument sample cup. Place the cup on the instrument and assay.

Limitations

CEDIA MPA Calibrators should not be used pwast the expiration date. If there is evidence of microbial contamination in the product, discard the vial.

Quality Control

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

A Precautions and Warnings

DANGER: CEDIA MPA Calibrator contains ≤10% bovine albumin serum (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.

Exercise the normal precautions required for handling all laboratory reagents.

CEDIA MPA Calibrators contain ≤0.09% of sodium azide, which may react with lead or copper plumbing to form metal azides. Continuous build-up of metal azides can present an explosion hazard. Upon disposal, flush drains with copious amounts of water to prevent azide build-up.

Glossary:

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

Microgenics Corporation 46500 Kato Road Fremont, CA 94538 USA US Customer and Technical Support: 1-800-232-3342



EC REP B·R·A·H·M·S GmbH Neuendorfstrasse 25 16761 Hennigsdorf, Germany

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

Other countries: Please contact your Thermo Fisher Scientific representative.