

QMS[®] Everolimus (EVER) Calibrators

IVD For In Vitro Diagnostic Use Only

REF 0373860

This Quantitative Microsphere System (QMS) package insert must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Intended Use

The QMS[®] Everolimus Calibrator set is intended for use in calibration of the QMS Everolimus assay.

Contents

The QMS Everolimus Calibrator set consists of human blood hemolysate and $\leq 1.0\%$ preservative with the following concentrations of everolimus:

Vial	Concentration (ng/mL)	Quantity	Fill Volume
A	0.0	1	3.00 mL
B	1.5	1	3.00 mL
C	3.0	1	3.00 mL
D	6.0	1	3.00 mL
E	12.0	1	3.00 mL
F	20.0	1	3.00 mL

Standardization

The reference material used to verify the accuracy of the QMS Everolimus Calibrators is of the highest quality available; its purity and composition were determined by HPLC. The material was prepared by gravimetric addition to human blood hemolysate. Each lot of calibrators is traceable to master calibrators that in turn have been value assigned to minimize the bias between an LC-MS/MS method and the QMS method for a set of trough samples from renal transplant patients.

Warnings and Precautions

Precautions For Users

- **For In Vitro Diagnostic Use.**
- Do not use components beyond the expiration date.
- The calibrators in this set are designed for use as a unit. Do not substitute or mix calibrators with those from other lots.

CAUTION/WARNING: This product contains human sourced and/or potentially infectious components. Components sourced from human blood have been tested and found to be nonreactive for HBsAg, anti-HIV 1/2, and anti-HCV. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, it is recommended that all human sourced materials be considered potentially infectious and handled with appropriate biosafety practices.

H412 - Harmful to aquatic life with long lasting effects.

Avoid release to the environment. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Instructions For Use

- Refer to the QMS Everolimus assay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- Calibrators are frozen. Thaw completely before use.
- Mix each calibrator by gentle inversion several times before dispensing.
- After each use, tightly close the caps and return calibrators to 2 to 8°C.

CAUTION: Bubbles may interfere with proper detection of calibrator level in the sample cup, causing insufficient calibrator aspiration that could impact results.

Storage and Stability

- Calibrators must be stored frozen ($-20 \pm 5^\circ\text{C}$) until first use.
- After first use calibrators are stable for 6 weeks, store tightly capped at 2 to 8°C.
- Do not allow the calibrators to remain at room temperature longer than is required to perform the assay.
- Do not use the calibrators beyond the expiration date.
- Light may affect calibrator stability. Keep stored calibrators out of light.

Indications of Instability or Deterioration

Instability or deterioration should be suspected if there are visible signs of leakage, turbidity, microbial growth, or if the assay does not meet the reagent package insert and/or instrument-specific operation manual criteria.

Limitations of the Procedure

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, storage of product as directed and good laboratory technique.

Glossary:

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



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