QMS® Everolimus (EVER) Controls

thermo scientific

IVD **For In Vitro Diagnostic Use Only**

Rx Only

REF **0373878**

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 Control set is intended for use in quality control of the QMS Everolimus assay.

Contents
The QMS Everolimus Control set consists of human blood hemolysate with the following concentrations of everolimus:

Vial	Concentration (ng/mL)	Quantity	Fill Volume
Level 1	Low	1	3.00 mL
Level 2	Medium	1	3.00 mL
Level 3	High	1	3.00 mL

Each laboratory should establish its own ranges for each new lot of controls.

Warnings and Precautions
Precautions For Users
- **For In Vitro Diagnostic Use.**
- The controls in this set are designed for use as a unit. Do not substitute or mix controls 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
- All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.
- Refer to the QMS Everolimus assay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- The QMS Everolimus Controls are **only** for use with the QMS Everolimus Assay.
- Controls are frozen. Thaw completely before use.
- Mix each control well by inversion several times before dispensing (use of a rocker is preferred). Avoid the formation of bubbles.
- After each use, tightly close the caps and return controls to 2 to 8°C.

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

Storage and Stability
- Controls must be stored frozen (-20 ± 5°C) until first use.
- After first use controls are stable for 6 weeks, store tightly capped at 2 to 8°C.
- Do not allow the controls to remain at room temperature longer than is required to perform the assay.
- Do not use the controls beyond the expiration date.
- Light may affect control stability. Keep stored controls 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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For insert updates go to:
www.thermofisher.com/diagnostics

Other countries:
Please contact your local Thermo Fisher Scientific representative.

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