QMS® Topiramate (TPM) Controls

Thermo SCIENTIFIC

IVD **For In Vitro Diagnostic Use Only**

Rx Only

REF **0374181**

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

Contents
The QMS Topiramate Control set consists of human serum with the following control levels of topiramate:

Vial	Control Level	Quantity	Fill Volume
Level 1	Low	1	2.0 mL
Level 2	Medium	1	2.0 mL
Level 3	High	1	2.0 mL

Each laboratory should establish its own range for each new lot of controls. See enclosed control-range card for each specific lot.

⚠ 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:** 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.

WARNING: QMS Topiramate (TPM) Controls contain ≤0.10% Sodium azide.
EUH032 - Contact with acids liberates very toxic gas.

Instructions For Use
- Refer to the QMS Topiramate assay package insert, included in the reagen kit, for a complete summary and explanation of the test.
- Controls may be used immediately upon removal from 2 to 8°C storage. **Note:** Upon first use, controls must be thoroughly thawed.
- Mix each control by gentle inversion several times before dispensing.
- After each use, tightly close the caps and return controls to 2 to 8°C.

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

Storage and Stability


- Controls must be stored frozen (≤-10°C) until first use.
- After first use, store controls tightly capped at 2 to 8°C. **Do not refreeze.**
- Do not expose the controls to temperatures above 32°C. Improper storage of controls can affect assay performance.

- Controls are stable at 2 to 8°C for 16 weeks after thawing.
- Do not use the controls beyond the expiration date.

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 operations 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.

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

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

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