QMS® Topiramate (TPM) Calibrators

Thermo SCIENTIFIC

IVD **For In Vitro Diagnostic Use Only**

Rx Only

REF **0374173**

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 Calibrator set is intended for use in calibration of the QMS Topiramate assay.

Contents
The QMS Topiramate Calibrator set consists of human serum and ≤0.10% sodium azide as preservative with the following concentrations of topiramate:

Vial	Concentration (µg/mL)	Quantity	Fill Volume
A	0.0	1	1.0 mL
B	2.0	1	1.0 mL
C	4.0	1	1.0 mL
D	8.0	1	1.0 mL
E	16.0	1	1.0 mL
F	32.0	1	1.0 mL

Standardization
There is no internationally recognized standard for Topiramate. The QMS Topiramate Calibrators are prepared by gravimetric dilution of high purity topiramate into human serum free of topiramate.

⚠ Warnings and Precautions
Precautions for Users
- For in vitro diagnostic use.
- The calibrators in this set are designed for use as a unit. Do not substitute or mix calibratos 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) Calibrators 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.
- Calibrators may be used immediately upon removal from 2 to 8°C.
- Mix each calibrator by gentle inversion several times before dispensing.
- Carefully squeeze at least for (4) drops of each calibrator into the individual sample cups, avoiding the formation of bubbles.
- 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 aspiration that could impact results.

Storage and Stability
- Do not expose the calibrators to temperatures above 32°C. Improper storage of calibrators can affect assay performance.
- After first use, the calibratos are stable until the expiration date when stored tightly capped at 2 to 8°C.
- Do not use the calibrators 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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