QMS® Lamotrigine (LTG) Controls

IVD **For In Vitro Diagnostic Use Only**

Rx Only

REF **0374090**

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

Contents

The QMS Lamotrigine Control set consists of human serum with the following concentrations of lamotrigine:

Vial	Concentration (µg/mL)	Quantity	Fill Volume
Level 1	2.0	1	2.5 mL
Level 2	15.0	1	2.5 mL
Level 3	25.0	1	2.5 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.

⚠ **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.

Instructions For Use

- Refer to the QMS Lamotrigine assay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- Controls may be used immediately upon removal from 2 to 8°C storage.
- 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 control level in the sample cup, causing insufficient control aspiration that could impact results.

Storage and Stability

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