

ARKTM Lamotrigine Control

This ARK Diagnostics, Inc. package insert for the ARK Lamotrigine Control must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Report any serious incident that has occurred in relation to the device to the manufacturer and the appropriate competent authority as applicable. A Summary of Safety and Performance is available through Eudamed (European database on medical devices), SRN: US-MF-000023925.

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Key to Symbols Used

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer

	Authorized Representative	 2797	CE Mark with notified body number
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Quality Control
Rx Only	For Prescription Use Only		

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Control Kit  5023-0003-00

1 Name

ARKTM *Lamotrigine Control*

2 Intended Use

ARK Lamotrigine Control is intended for use in quality control of the ARK Lamotrigine Assay, **REF** 5023-0001-00.

3 Content

ARK Lamotrigine Control is comprised of a synthetic protein matrix with the following concentrations of lamotrigine:

REF	Product Description	Quantity/Volume
5023-0003-00	ARK Lamotrigine Control* Lamotrigine, buffer, bovine serum albumin, and preservatives (nominal level)	Dropper vials
	LOW (2.00 µg/mL)	1 X 4 mL
	MID (12.00 µg/mL)	1 X 4 mL
	HIGH (25.00 µg/mL)	1 X 4 mL

* To convert results from µg/mL lamotrigine to µmol/L lamotrigine, multiply µg/mL by 3.90. Lamotrigine levels become 7.80, 46.80, and 97.50 µmol/L for trilevel controls respectively.

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

4 Warnings and Precautions

- For *In Vitro Diagnostic* Use.
- Do not mix controls from different lot numbers.
- Use each lot as a set.

5 Instructions For Use

- For a complete summary and explanation of the lamotrigine assay, refer to the package insert for the ARK Lamotrigine Assay.
- Controls are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume (~40µL/drop) into individual sample cups for each level. Consult instrument-specific sample volume requirements. Return caps to their original containers and keep tight.

- Store vials at 2-8°C. Once opened, use within 12 months and prior to the expiration date.

6 Limitations of Procedure

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

7 Trademarks

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