

ARK™ Lamotrigine Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Lamotrigine Calibrator 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.

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KEY TO SYMBOLS USED

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative		CE Mark
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Calibrator
Rx Only	For Prescription Use Only		

1 NAME

ARK™ Lamotrigine Calibrator

2 INTENDED USE

ARK Lamotrigine Calibrator is intended for use in calibration of the ARK Lamotrigine Assay,  5023-0001-00.

3 CONTENT

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

REF	Product Description	Quantity/Volume
5023-0002-00	ARK Lamotrigine Calibrators* Lamotrigine, buffer, bovine serum albumin, and preservatives	Dropper vials
	A	0.00 µg/mL 1 X 4 mL
	B	1.00 µg/mL 1 X 2 mL
	C	3.00 µg/mL 1 X 2 mL
	D	9.00 µg/mL 1 X 2 mL
	E	18.00 µg/mL 1 X 2 mL
	F	40.00 µg/mL 1 X 2 mL

* To convert results from µg/mL lamotrigine to µmol/L lamotrigine, multiply µg/mL by 3.90. Lamotrigine levels become 3.90, 11.70, 35.10, 70.20, and 156.00 µmol/L for Calibrators B to F respectively.

4 STANDARDIZATION

There is no internationally recognized standard for lamotrigine. ARK Lamotrigine Calibrators are prepared by gravimetric dilution of high purity lamotrigine into a synthetic proteinaceous matrix free of lamotrigine.

5 WARNINGS AND PRECAUTIONS

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

6 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the lamotrigine assay, refer to the package insert for the ARK Lamotrigine Assay.
- Calibrators 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. Use prior to the expiration date. Once opened, vials may be stored at 2-8°C for 12 months within the expiration date.

7 PROCEDURE

Calibration

Perform a full calibration (6- point) procedure; test calibrators in duplicate. Verify the calibration curve with at least two levels of quality controls according to the established laboratory quality assurance plan.

When to Re-Calibrate

- Whenever a new lot number of reagents is used
- Whenever indicated by quality control results
- Whenever required by standard laboratory protocols

8 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.

9 TRADEMARKS

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