
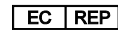


ARK™ Topiramate Calibrator











This ARK Diagnostics, Inc. package insert for the ARK Topiramate 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.

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.

Customer Service


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Key to Symbols Used

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

1 Name

ARK™ *Topiramate Calibrator*

2 Intended Use

ARK Topiramate Calibrator is intended for use in calibration of the ARK Topiramate Assay, REF 5015-0001-00.

3 Content

ARK Topiramate Calibrator is comprised of a synthetic protein matrix with the following concentrations of topiramate:

REF	Product Description	Quantity/Volume	
5015-0002-00	ARK Topiramate Calibrators Topiramate, buffer, bovine serum albumin, and preservatives	Dropper vials	
	A	0.0 µg/mL	1 X 4 mL
	B	2.0 µg/mL	1 X 2 mL
	C	4.0 µg/mL	1 X 2 mL
	D	8.0 µg/mL	1 X 2 mL
	E	24.0 µg/mL	1 X 2 mL
	F	60.0 µg/mL	1 X 2 mL

4 Standardization

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

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 topiramate assay, refer to the package insert for the ARK Topiramate 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 at 2-8°C. Once opened, use within 12 months and prior to 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

ARKTM is a trademark of **ARK** Diagnostics, Inc.

Other brand or product names are trademarks of their respective holders.



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