
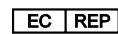


ARK™ Topiramate Control





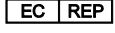





This ARK Diagnostics, Inc. package insert for the ARK Topiramate Control must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

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.

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		Quality Control
Rx Only	For Prescription Use Only		

1 Name

ARKTM Topiramate Control

2 Intended Use

ARK Topiramate Control is intended for use in quality control of the ARK Topiramate Assay, **REF** 5015-0001-00.

3 Content

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

REF	Product Description	Quantity/Volume
5015-0003-00	ARK Topiramate Control Topiramate, buffer, bovine serum albumin, and preservatives (nominal level)	Dropper vials
	LOW (2.5 µg/mL)	1 X 4 mL
	MID (10.0 µg/mL)	1 X 4 mL
	HIGH (40.0 µg/mL)	1 X 4 mL

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 topiramate assay, refer to the package insert for the ARK Topiramate 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 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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