

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.

Customer Service













48089 Fremont Blvd
Fremont, CA 94538 USA
Tel: 1-877-869-2320
Fax: 1-510-270-6298
customersupport@ark-tdm.com
www.ark-tdm.com



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands


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™ Topiramate Calibrator

2 Intended Use

ARK Topiramate Calibrator is intended for use in calibration of the ARK Topiramate Assay,  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 Calibrator Topiramate, buffer, bovine serum albumin, and preservatives | Dropper vials |
| | A | 0.0 µg/mL |
| | B | 2.0 µg/mL |
| | C | 4.0 µg/mL |
| | D | 8.0 µg/mL |
| | E | 24.0 µg/mL |
| | F | 60.0 µg/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. Use 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

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