ARK™ *Zonisamide Calibrator*

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

ARK Diagnostics, Inc.

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

CE
2797

EC REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Key to Symbols Used

LOT	Batch code	**YYYY-MM-DD**	Use by/Expiration date
REF	Catalog Number		Manufacturer
EC REP	Authorized Representative	CE **2797**	CE Mark with notified body number
IVD	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use	Calibrator	Calibrator
Rx Only	For Prescription Use Only		

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Calibrator Kit REF 5022-0002-00

1 Name

ARK™ ***Zonisamide Calibrator***

2 Intended Use

ARK Zonisamide Calibrator is intended for use in calibration of the ARK Zonisamide Assay, REF 5022-0001-00.

3 Content

ARK Zonisamide Calibrator is comprised of a synthetic protein matrix with the following concentrations of zonisamide:

REF	Product Description		Quantity/Volume
5022-0002-00	**ARK Zonisamide Calibrators** Zonisamide, buffer, bovine serum albumin, and preservatives		Dropper vials
	A	0.0 µg/mL	1 X 4 mL
	B	2.5 µg/mL	1 X 2 mL
	C	7.5 µg/mL	1 X 2 mL
	D	20.0 µg/mL	1 X 2 mL
	E	40.0 µg/mL	1 X 2 mL
	F	80.0 µg/mL	1 X 2 mL

4 Standardization

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

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 ARK Zonisamide Assay, refer to the package insert for the ARK Zonisamide Assay, REF 5022-0001-00.
- 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

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ARK Diagnostics, Inc.
Fremont, CA 94538 USA

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