ARK™ *Oxcarbazepine Metabolite Calibrator*

This ARK Diagnostics, Inc. package insert for the ARK Oxcarbazepine Metabolite 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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CE
2797

EC REP

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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
	Consult Instructions for Use	Calibrator	Calibrator
	Temperature limitation	IVD	In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

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Calibrator Kit REF 5032-0002-00

1 NAME

ARK™ *Oxcarbazepine Metabolite Calibrator*

2 INTENDED USE

ARK Oxcarbazepine Metabolite Calibrator is intended for use in calibration of the ARK Oxcarbazepine Metabolite Assay.

3 CONTENT AND TARGET VALUES

ARK Oxcarbazepine Metabolite Calibrator is comprised of a synthetic protein matrix with the following concentrations of Oxcarbazepine Metabolite.

REF	Product Description		Quantity/Volume
5032-0002-00	**ARK Oxcarbazepine Metabolite Calibrators*** Oxcarbazepine Metabolite, buffer, bovine serum albumin, and sodium azide		Dropper vials
	A	0.0 µg/mL	1 X 4 mL
	B	2.0 µg/mL	1 X 2 mL
	C	5.0 µg/mL	1 X 2 mL
	D	12.0 µg/mL	1 X 2 mL
	E	25.0 µg/mL	1 X 2 mL
	F	50.0 µg/mL	1 X 2 mL

*To convert results from µg/mL to µmol/L Oxcarbazepine Metabolite, multiply µg/mL by 3.933. Oxcarbazepine Metabolite levels become 7.9, 19.7, 47.2, 98.3, and 196.6 µmol/L for Calibrators B to F respectively.

4 STANDARDIZATION

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

5 WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic Use. For prescription use only.
- Do not mix calibrators from different lot numbers.
- Use each lot as a set.
- Calibrators contain ≤0.09% sodium azide.

6 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the Oxcarbazepine Metabolite assay, refer to the package insert for the ARK Oxcarbazepine Metabolite 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. Once opened, use within 12 months and prior to the expiration date.

7 PROCEDURE

Calibration
Perform a calibration using the ARK Oxcarbazepine Metabolite Calibrators A, B, C, D, E, and F. Verify the calibration curve with 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

A stored calibration curve was effective up to 15 days based on supporting data.

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.

All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

9 TRADEMARKS

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