ARK™ *Oxcarbazepine Metabolite Control*

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

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	CONTROL	Quality Control
	Temperature limitation	IVD	In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

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Control Kit REF 5032-0003-00

1 NAME

ARK™ *Oxcarbazepine Metabolite Control*

2 INTENDED USE

ARK Oxcarbazepine Metabolite Control is an assayed quality control material intended for use in quality control of the ARK Oxcarbazepine Metabolite Assay.

3 CONTENT AND TARGET VALUES

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

REF	Product Description	Quality Control
5032-0003-00	**ARK Oxcarbazepine Metabolite Control* (4 mL)** Oxcarbazepine Metabolite, buffer, bovine serum albumin, and sodium azide (target level)	Expected Range (Mean µg/mL)
	LOW (3.0 µg/mL)	2.4 – 3.6
	MID (10.0 µg/mL)	8.5 – 11.5
	HIGH (30.0 µg/mL)	25.0 – 35.0

*To convert results from µg/mL to µmol/L Oxcarbazepine Metabolite, multiply µg/mL by 3.933. Oxcarbazepine Metabolite levels become 11.8, 39.3 and 118.0 µmol/L for LOW, MID and HIGH respectively.

Value Assignment: Testing is performed with the ARK Oxcarbazepine Metabolite Assay on the Beckman Coulter AU480® automated analyzer, calibrated with the master calibrator lot. Three calibrated runs are performed using four replicates of each level per run. The expected control ranges are set according to mean values. Each laboratory should establish the mean value for each control level and its own ranges for each new lot of controls.

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 controls from different lot numbers.
- Use each lot as a set.
- Controls 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.
- 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 vials at 2-8°C. Once opened, use within 12 months and prior to the expiration date.

7 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.

8 TRADEMARKS

ARK™ is a trademark of ARK Diagnostics, Inc.
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