

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.

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

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 at 2-8°C. Use prior to the expiration date. Once opened vials may be stored at 2-8°C for 12 months within 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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