ARK Diagnostics, Inc.

ARK™ *Lacosamide Control*

This ARK Diagnostics, Inc. package insert for the ARK Lacosamide 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. The ARK Lacosamide Assay test system includes separately provided test kits for the ARK Lacosamide Assay, ARK Lacosamide Calibrator and ARK Lacosamide Control.

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	CE Mark
	Consult Instructions for Use	CONTROL	Quality Control
	Temperature limitation	IVD	*In Vitro* Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ *Lacosamide Control*

2 INTENDED USE

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

3 CONTENT

ARK Lacosamide Control is an assayed control comprised of a synthetic protein matrix with the following target concentrations of lacosamide:

REF	Product Description	Quality Control
5033-0003-00	**ARK Lacosamide Control* (4 mL)** Lacosamide, buffer, bovine serum albumin, and sodium azide	Expected Range (Mean µg/mL)
	LOW (1.50 µg/mL)	1.20 – 1.80
	MID (7.00 µg/mL)	5.60 – 8.40
	HIGH (15.00 µg/mL)	12.00 – 18.00

*To convert results from µg/mL lacosamide to µmol/L lacosamide, multiply µg/mL by 3.995. Lacosamide levels become 5.99, 27.96 and 59.92 µmol/L for LOW, MID and HIGH respectively.

Value Assignment: Testing is performed with the ARK Lacosamide Assay on the Beckman Coulter AU680 automated analyzer, calibrated with the ARK Lacosamide Calibrator. Two calibrated runs are performed using five replicates of each level per run. Mean values (10 replicates) for the test lots are expected to result within 10% of the nominal concentration. Expected control ranges are set to be +/- 20% from mean values.

Each laboratory should establish its own ranges for each new lot of controls based on its own test system and criteria.

4 STANDARDIZATION

There is no internationally recognized standard for lacosamide. ARK Lacosamide Controls are prepared by volumetric dilution of high purity lacosamide (Cerilliant) into a synthetic proteinaceous matrix free of lacosamide.

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 lacosamide assay, refer to the package insert for the ARK Lacosamide 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 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 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

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