

ARK™ *Gabapentin Control*

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

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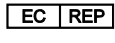





EC REP

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 Westervoortsedijk 60
 6827 AT Arnhem
 The Netherlands

CH REP

MedEnvoy Switzerland
 Gotthardstrasse 28
 6302 Zug
 Switzerland

Key to Symbols Used

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative		CE Mark with notified body number
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Quality Control
Rx Only	For Prescription Use Only		

1 Name

ARKTM Gabapentin Control

2 Intended Use

ARK Gabapentin Control is intended for use in quality control of the ARK Gabapentin Assay.

3 Content

ARK Gabapentin Control is comprised of a synthetic protein matrix with the following concentrations of Gabapentin:

REF	Product Description	Quantity/Volume
5025-0003-00	ARK Gabapentin Control* Gabapentin, buffer, bovine serum albumin, and sodium azide (nominal level)	Dropper vials
	LOW (2.5 µg/mL)	1 X 4 mL
	MID (8.0 µg/mL)	1 X 4 mL
	HIGH (25.0 µg/mL)	1 X 4 mL

* To convert results from µg/mL gabapentin to µmol/L gabapentin, multiply µg/mL by 5.84. Gabapentin levels become 14.6, 46.7, and 146.0 µmol/L for trilevel controls respectively.

Each laboratory should establish its own ranges for each new lot of controls.

4 Warnings and Precautions

- For *In Vitro* Diagnostic Use.
- Do not mix controls from different lot numbers.
- Use each lot as a set.
- Controls contain ≤0.09% sodium azide.

5 Instructions For Use

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

6 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.

7 Trademarks

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