

ARK™ *Levetiracetam Calibrator*

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



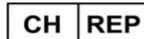
ARK Diagnostics, Inc.

48089 Fremont Blvd
 Fremont, CA 94538 USA
 Tel: 1-877-869-2320
 Fax: 1-510-270-6298
 customersupport@ark-tdm.com
 www.ark-tdm.com







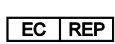

2797





Emergo Europe
 Westervoortsedijk 60
 6827 AT Arnhem
 The Netherlands



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		Calibrator
Rx Only	For Prescription Use Only		

© 2025, **ARK** Diagnostics, Inc.

Calibrator Kit  **5024-0002-00**

1 Name

ARKTM *Levetiracetam Calibrator*

2 Intended Use

ARK Levetiracetam Calibrator is intended for use in calibration of the ARK Levetiracetam Assay, REF 5024-0001-00.

3 Content

ARK Levetiracetam Calibrator is comprised of a synthetic protein matrix with the following concentrations of levetiracetam:

REF	Product Description	Quantity/Volume	
5024-0002-00	ARK Levetiracetam Calibrators Levetiracetam, buffer, bovine serum albumin, and preservatives	Dropper vials	
	A	0.0 µg/mL	1 X 4 mL
	B	5.0 µg/mL	1 X 2 mL
	C	12.5 µg/mL	1 X 2 mL
	D	25.0 µg/mL	1 X 2 mL
	E	50.0 µg/mL	1 X 2 mL
	F	100.0 µg/mL	1 X 2 mL

4 Standardization

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

5 Warnings and Precautions

- For *In Vitro* Diagnostic Use.
- Do not mix calibrators from different lot numbers.
- Use each lot as a set.

6 Instructions For Use

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

7 Procedure

Calibration

Perform a full calibration (6- point) procedure; test calibrators in duplicate. Verify the calibration curve with at least two levels of 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

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.

9 Trademarks

ARKTM is a trademark of **ARK** Diagnostics, Inc.

Other brand or product names are trademarks of their respective holders.



ARK Diagnostics, Inc.
Fremont, CA 94538 USA

Revised January 2025
1600-0170-00 Rev 06