



ARK™ Linezolid Calibrator

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

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



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



Emergo Europe
 Westervoortsedijk 60
 6827 AT Arnhem
 The Netherlands

Key to Symbols Used

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

1 Name

ARKTM Linezolid Calibrator

2 Intended Use

The ARK Linezolid Calibrator is intended for use in calibration of the ARK Linezolid Assay.

3 Content

The ARK Linezolid Calibrator is comprised of a synthetic protein matrix with the following concentrations of linezolid:

REF	Product Description	Quantity/Volume	
5034-0002-00	ARK Linezolid Calibrators* Linezolid, buffer, bovine serum albumin, and sodium azide	Dropper Vials	
	A	0.0 µg/mL	1 X 4 mL
	B	1.0 µg/mL	1 X 2 mL
	C	2.5 µg/mL	1 X 2 mL
	D	5.0 µg/mL	1 X 2 mL
	E	15.0 µg/mL	1 X 2 mL
	F	30.0 µg/mL	1 X 2 mL

*To convert results from µg/mL linezolid to µmol/L linezolid, multiply µg/mL by 2.964. Linezolid levels become 2.96, 7.41, 14.82, 44.46, and 88.92 µmol/L for Calibrators B to F respectively.

The measurement range of the ARK Linezolid Assay is 0.75 – 30.00 µg/mL.

4 Standardization

There is no internationally recognized standard for linezolid. ARK Linezolid Calibrators are prepared by gravimetric dilution of high purity linezolid (traceable to HPLC) into a synthetic proteinaceous matrix free of linezolid.

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 linezolid assay, refer to the package insert for the ARK Linezolid Assay.
- Calibrators are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume (~40 µL/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 calibration using the ARK Linezolid 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 at least 14 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

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

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