

For Export Only – Not For Sale in USA

ARK™ Voriconazole II Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Voriconazole II 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

 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



Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands
Tel: (31) (0) 70 345-8570
Fax: (31) (0) 70 346-7299

KEY TO SYMBOLS USED

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative		CE Mark
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Calibrator

1 NAME

ARK™ Voriconazole II Calibrator

2 INTENDED USE

ARK Voriconazole II Calibrator is intended for use in calibration of the ARK Voriconazole II Assay.

3 CONTENT

ARK Voriconazole II Calibrator is comprised of a synthetic protein matrix with the following concentrations of voriconazole:

REF	Product Description	Quantity/Volume	
5030-0002-01	ARK Voriconazole II Calibrators* Voriconazole, buffer, bovine serum albumin, and sodium azide	Dropper vials	
	A	0.0 µg/mL	1 X 4 mL
	B	0.5 µg/mL	1 X 2 mL
	C	1.5 µg/mL	1 X 2 mL
	D	4.0 µg/mL	1 X 2 mL
	E	8.0 µg/mL	1 X 2 mL
	F	16.0 µg/mL	1 X 2 mL

*To convert results from µg/mL voriconazole to µmol/L voriconazole, multiply µg/mL by 2.863. Voriconazole levels become 1.4, 4.3, 11.4, 22.9, and 45.8 µmol/L for Calibrators B to F respectively.

4 STANDARDIZATION

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

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 voriconazole assay, refer to the package insert for the ARK Voriconazole II 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 Voriconazole II 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

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

ARK™ is a trademark of ARK Diagnostics, Inc.

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