

For Export Only – Not For Sale in USA

ARK™ Voriconazole II Control

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

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		Quality Control

1 NAME

ARK™ Voriconazole II Control

2 INTENDED USE

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

3 CONTENT

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

REF	Product Description	Quality Control
5030-0003-01	ARK Voriconazole II Control* (4 mL) Voriconazole, buffer, bovine serum albumin, and sodium azide (nominal level)	Expected Range (µg/mL)
	LOW (1.0 µg/mL)	0.8 – 1.2
	MID (5.0 µg/mL)	4.0 – 6.0
	HIGH (10.0 µg/mL)	8.0 – 12.0

* To convert results from µg/mL voriconazole to µmol/L voriconazole, multiply µg/mL by 2.863. Voriconazole levels become 2.9, 14.3, and 28.6 µmol/L for trilevel controls respectively.

Each laboratory should establish its own ranges for each new lot of controls. The ARK Voriconazole II Control is a non-assayed control intended for monitoring reproducibility.

4 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.

5 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the voriconazole assay, refer to the package insert for the ARK Voriconazole II 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.

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

ARK™ is a trademark of ARK Diagnostics, Inc.

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