

# ARK<sup>™</sup> 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. The ARK Voriconazole II Assay test system includes separately provided test kits for the ARK Voriconazole II Assay, ARK Voriconazole II Calibrator and ARK Voriconazole II Control.

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### **KEY TO SYMBOLS USED**

LOT	Batch code	YYYY- MM-DD	Use by/Expiration date
REF	Catalog Number	<b></b>	Manufacturer
EC REP	Authorized Representative	CE	CE Mark
Ţi	Consult Instructions for Use	CALIBRATOR	Calibrator
	Temperature limitation	IVD	In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

#### 1 NAME

# ARK<sup>™</sup> 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
	В	0.5 µg/mL	1 X 2 mL
	С	1.5 µg/mL	1 X 2 mL
	D	4.0 µg/mL	1 X 2 mL
	Е	8.0 µg/mL	1 X 2 mL
	F	16.0 µg/mL	1 X 2 mL

<sup>\*</sup>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.

The measurement range of the ARK Voriconazole II Assay is 0.5 – 14.0 µg/mL.

## **4 STANDARDIZATION**

There is no internationally recognized standard for voriconazole. ARK Voriconazole II Calibrators are prepared by gravimetric dilution of high purity voriconazole (USP Reference Standard) into a synthetic proteinaceous matrix free of voriconazole. The ARK Voriconazole II Calibrator is traceable to a certified reference standard (USP) and the uncertainty in the voriconazole concentration is 5% relative to the concentration in the certified reference standard

#### **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

A stored calibration curve was effective up to at least 30 days based on supporting data.

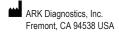
## **8 LIMITATIONS OF PROCEDURE**

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

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