

ARKTM 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. 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.

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

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EC REP

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Key to Symbols Used

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer

	Authorized Representative	 2797	CE Mark with notified body number
	Consult Instructions for Use		Quality Control
	Temperature limitation		In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

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Control Kit  **5030-0003-01**

1 Name

ARKTM Voriconazole II Control

2 Intended Use

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

3 Content

ARK Voriconazole II Control is an assayed control comprised of a synthetic protein matrix with the following target 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	Expected Range (Mean 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 LOW, MID and HIGH respectively.

Value Assignment: Testing is performed with the ARK Voriconazole II Assay on the Roche cobas[®] c501 automated analyzer, calibrated with the ARK Voriconazole II Calibrator. Two calibrated runs are performed using five replicates of each level per run. Mean values (10 replicates) for the test lots are expected to result within 10% of the nominal concentration. Expected control ranges are set to be +/- 20% from mean values.

Each laboratory should establish its own ranges for each new lot of controls based on its own test system and criteria.

4 STANDARDIZATION

There is no internationally recognized standard for voriconazole. ARK Voriconazole II Controls are prepared by gravimetric dilution of high purity voriconazole (USP Reference Standard) into a synthetic proteinaceous matrix free of voriconazole.

5 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 $\leq 0.09\%$ 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.
- Controls are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume ($\sim 40\mu\text{L}/\text{drop}$) 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.

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.

All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

7 Trademarks

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