ARK Diagnostics, Inc.

For Export Only – Not For Sale in USA

ARK™ *Apixaban Control*

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

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Key to Symbols Used

LOT	Batch code	YYYY-MM-DD	Use by/Expiration date
REF	Catalog Number		Manufacturer
EC REP	Authorized Representative	CE 2797	CE Mark with notified body number
	Consult Instructions for Use	CONTROL	Quality Control
	Temperature limitation	IVD	In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

Control Kit REF 5047-0003-00

1 Name

ARK™ *Apixaban Control*

2 Intended Use

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

3 Content

ARK Apixaban Control is an assayed control comprised of a synthetic protein matrix with the following target concentrations of apixaban:

REF	Product Description	Quality Control
5047-0003-00	**ARK Apixaban Control* (4 mL)** Apixaban, buffer, bovine serum albumin, and sodium azide	Expected Range (Mean ng/mL)
	LOW (10.0 ng/mL)	8.0 – 12.0
	MID (30.0 ng/mL)	24.0 – 36.0
	HIGH (200.0 ng/mL)	160.0 – 240.0

*To convert results from ng/mL apixaban to nmol/L apixaban, multiply ng/mL by 2.176. Apixaban levels become 21.76, 65.28, and 435.2 nmol/L for LOW, MID and HIGH respectively.

Value Assignment: Testing is performed with the ARK Apixaban Assay on the Beckman Coulter AU680 automated analyzer, calibrated with the ARK Apixaban 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 apixaban. ARK Apixaban Controls are prepared by volumetric dilution of high purity, certified apixaban into a synthetic proteinaceous matrix free of apixaban.

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 ≤0.09% sodium azide.

6 Instructions For Use

- For a complete summary and explanation of the apixaban assay, refer to the package insert for the ARK Apixaban 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 vials at 2-8°C. Once opened, use within 12 months and prior to the expiration date.

7 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.

8 Trademarks

ARK Diagnostics, Inc.
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