



For Export Only – Not For Sale in USA

ARK™ Apixaban Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Apixaban 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 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

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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		Calibrator
	Temperature limitation		In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 Name

ARKTM Apixaban Calibrator

2 Intended Use

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

3 Content

ARK Apixaban Calibrator is comprised of a synthetic protein matrix with the following concentrations of apixaban:

REF	Product Description		Quantity/Volume
5047-0002-00	ARK Apixaban Calibrators* Apixaban, buffer, bovine serum albumin, and sodium azide		Dropper vials
	A	0.0 ng/mL	1 X 4 mL
	B	5.0 ng/mL	1 X 2 mL
	C	20.0 ng/mL	1 X 2 mL
	D	50.0 ng/mL	1 X 2 mL
	E	100.0 ng/mL	1 X 2 mL
	F	400.0 ng/mL	1 X 2 mL

*To convert results from ng/mL apixaban to nmol/L apixaban, multiply ng/mL by 2.176. Apixaban levels become 10.9, 43.5, 108.8, 217.6 and 870.4 nmol/L for Calibrators B to F respectively.

The measurement range of the ARK Apixaban Assay is 3.0 – 400.0 ng/mL.

4 Standardization

There is no internationally recognized standard for apixaban. ARK Apixaban Calibrators are prepared by volumetric dilution of high purity, certified apixaban into a synthetic proteinaceous matrix free of apixaban.

The ARK Apixaban Calibrator is traceable to a certified reference standard and the uncertainty in the apixaban 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 $\leq 0.09\%$ 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.
- Calibrators 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 vials at $2-8^{\circ}\text{C}$. Once opened, use within 12 months and prior to the expiration date.

7 Procedure

Calibration

Perform a calibration using the ARK Apixaban 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 14 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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