

For Export Only – Not For Sale in USA

ARK™ AB-PINACA Calibrator

This ARK Diagnostics, Inc. package insert for the ARK AB-PINACA 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.

CUSTOMER SERVICE

 ARK Diagnostics, Inc.











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KEY TO SYMBOLS USED

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	Authorized Representative		CE Mark
	Consult Instructions for Use		Calibrator
	Temperature limitation		<i>In Vitro</i> Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ AB-PINACA Calibrator

2 INTENDED USE

The ARK AB-PINACA Calibrator is intended for use in calibration of the ARK AB-PINACA Assay.

3 CONTENT

The ARK AB-PINACA Negative Calibrator is composed of a non-sterile, processed human urine matrix. The ARK AB-PINACA Cutoff Calibrator is composed of non-sterile, processed human urine containing 5 ng/mL of AB-PINACA Pentanoic Acid.

REF	Product Description	Quantity/Volume
5055-0002-01	ARK AB-PINACA Negative Calibrator Human urine, stabilizer and sodium azide	Dropper Vials
	Negative	0 ng/mL 2 X 10 mL

REF	Product Description	Quantity/Volume
5055-0002-02	ARK AB-PINACA Cutoff Calibrator AB-PINACA Pentanoic Acid, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	5 ng/mL 2 X 10 mL

4 STANDARDIZATION

There is no internationally recognized standard for AB-PINACA Pentanoic Acid. A certified solution of AB-PINACA Pentanoic Acid is traceable to HPLC. ARK AB-PINACA Calibrators are prepared by volumetric dilution of high purity AB-PINACA Pentanoic Acid into non-sterile, processed human urine.

Calibrators are made with non-sterile, processed human urine. Donors were non-reactive in tests for HIV 1/2, HBsAg, HCV, HIV-1 (NAT), HCV (NAT) and RPR.

5 WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use. For prescription use only.
- Harmful if swallowed.
- Contains human urine. Handle as potentially infectious.
- Product contains ≤0.09% sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately with water to mitigate the potential accumulation of explosive metal azides.

6 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the AB-PINACA Assay, refer to the package insert for the ARK AB-PINACA 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.

7 PROCEDURE

Qualitative Results

Use the 5 ng/mL Cutoff Calibrator to distinguish negative and positive samples. Run the Low and High Controls as Negative and Positive respectively. Report test results less than the response value for the Cutoff Calibrator as Negative. Report test results equal to or greater than the response value for the Cutoff Calibrator as Positive.

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 29 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.


9 TRADEMARKS

ARK™ is a trademark of ARK Diagnostics, Inc.

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

Negative Kit  5055-0002-01

Cutoff Kit  5055-0002-02

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Printed in USA
Revised May 2019
1600-0922-00 Rev 01