



ARK™ EDDP Calibrator

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

Report any serious incident that has occurred in relation to the device to the manufacturer and the appropriate competent authority as applicable.

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 Gotthardstrasse 28
 6302 Zug
 Switzerland

Key to Symbols Used

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

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Calibrator Kit 5051-0002-00

Negative Kit 5051-0002-01

Cutoff Kit 5051-0002-02; 5051-0002-03

1 Name

ARK™ EDDP Calibrator

2 Intended Use

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

3 Content

The ARK EDDP Calibrator is composed of a non-sterile, processed human urine matrix with the following concentrations of EDDP. Negative and Cutoff calibrators may be obtained separately for qualitative analysis.

REF	Product Description	Quantity/Volume	
5051-0002-00	ARK EDDP Calibrator EDDP, human urine, stabilizer and sodium azide	Dropper Vials	
	A	0 ng/mL	1 X 10 mL
	B	100 ng/mL	1 X 10 mL
	C	300 ng/mL	1 X 10 mL
	D	500 ng/mL	1 X 10 mL
	E	1000 ng/mL	1 X 10 mL

REF	Product Description	Quantity/Volume
5051-0002-01	ARK EDDP Calibrator A (Negative) Human urine, stabilizer and sodium azide	Dropper Vials
	Negative	0 ng/mL

REF	Product Description	Quantity/Volume
5051-0002-02	ARK EDDP Calibrator B (Cutoff) EDDP, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	100 ng/mL

REF	Product Description	Quantity/Volume
5051-0002-03	ARK EDDP Calibrator C (Cutoff) EDDP, human urine, stabilizer and sodium azide	Dropper Vials
	Cutoff	300 ng/mL

4 Standardization

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

Calibrators are made with non-sterile, processed human urine free of EDDP. 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.
- Do not mix calibrators from different lot numbers.
- Use each lot as a set.
- Product contains $\leq 0.09\%$ 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 EDDP Assay, refer to the package insert for the ARK EDDP 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°C. Once opened, use within 12 months and prior to the expiration date.

7 Procedure

Qualitative Results

Use the 100 ng/mL Calibrator B or the 300 ng/mL Calibrator C as a Cutoff Calibrator to distinguish negative and positive samples. Run the ARK EDDP Low (75 ng/mL) and High (125 ng/mL) Controls with Cutoff Calibrator B or the ARK EDDP Low (225 ng/mL) and High (375 ng/mL) Controls with Cutoff Calibrator C, as Negative and Positive respectively. Report test results less than the response value for the applicable Cutoff Calibrator as Negative. Report test results equal to or greater than the response value for the applicable Cutoff Calibrator as Positive.

Semiquantitative Results

Perform a 5-point calibration procedure; run calibrators in duplicate. Verify the calibration curve with the ARK EDDP Low and High quality controls according to the established laboratory quality assurance plan. Specimens with sample results above the highest ARK EDDP calibrator level (1000 ng/mL) may be diluted in ARK EDDP Calibrator A (Negative urine) and retested.

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 15 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

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



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Revised July 2025
1600-0871-00 Rev 04