



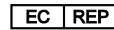
This ARK Diagnostics, Inc. package insert for the ARK EDDP Control must be read carefully prior to use. Package insert instructions must be followed accordingly. Reliability of the assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

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

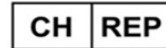
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Key to Symbols Used

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

1 Name

ARK™ EDDP Control

2 Intended Use

The ARK EDDP Control is intended for use in quality control of the ARK EDDP Assay.

3 Content

The ARK EDDP Control is composed of a non-sterile, processed human urine matrix with the following target concentrations of EDDP.

For use with Cutoff Calibrator B (100 ng/mL):

REF	Product Description	Quantity/Volume
5051-0003-00	ARK EDDP Control EDDP, human urine, stabilizer and sodium azide	Dropper Vials
	LOW / Negative (75 ng/mL)	2 X 10 mL
	HIGH / Positive (125 ng/mL)	2 X 10 mL

For use with Cutoff Calibrator C (300 ng/mL):

REF	Product Description	Quantity/Volume
5051-0003-01	ARK EDDP Control EDDP, human urine, stabilizer and sodium azide	Dropper Vials
	LOW / Negative (225 ng/mL)	2 X 10 mL
	HIGH / Positive (375 ng/mL)	2 X 10 mL

Traceability and Value Assignment: A certified solution of EDDP is traceable to HPLC. Testing is performed with the ARK EDDP Assay calibrated with the ARK EDDP Calibrator.

Each laboratory should establish its own ranges for each new lot of controls. Control results should fall within established ranges as determined by laboratory procedures and guidelines.

In Qualitative Mode, the Low Control should be Negative and the High Control should be Positive relative to the applicable Cutoff Calibrator (100 ng/mL or 300 ng/mL).

Controls 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.

4 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 controls 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.

5 Instructions For Use

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

7 Trademarks

ARK[™] is a trademark of ARK Diagnostics, Inc.

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



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