

For Export Only – Not For Sale in USA

ARK™ Efavirenz Control

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

CUSTOMER SERVICE

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

1 NAME

ARK™ Efavirenz Control

2 INTENDED USE

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

3 CONTENT

ARK Efavirenz Control is comprised of a synthetic protein matrix with the following concentrations of efavirenz:

REF	Product Description	Quality Control
5017-0003-00	ARK Efavirenz Control* (4 mL) Efavirenz, buffer, bovine serum albumin, and sodium azide (nominal level)	Expected Range (µg/mL)
	LOW (1.0 µg/mL)	0.8 – 1.2
	MID (4.0 µg/mL)	3.2 – 4.8
	HIGH (8.0 µg/mL)	6.4 – 9.6

*To convert results from µg/mL efavirenz to µmol/L efavirenz, multiply µg/mL by 3.168. Efavirenz levels become 3.2, 12.7, and 25.3 µmol/L for trilevel controls respectively.

Each laboratory should establish its own ranges for each new lot of controls. The ARK Efavirenz Control is a non-assayed control intended for monitoring reproducibility.

4 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.

5 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the efavirenz assay, refer to the package insert for the ARK Efavirenz 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 at 2-8°C. Use prior to the expiration date. Once opened vials may be stored at 2-8°C for 12 months within 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

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