

For Export Only – Not For Sale in USA

ARK™ Efavirenz Calibrator

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

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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		In Vitro Diagnostic Medical Device
Rx Only	For Prescription Use Only		

1 NAME

ARK™ Efavirenz Calibrator

2 INTENDED USE

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

3 CONTENT

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

REF	Product Description	Quantity/Volume
5017-0002-00	ARK Efavirenz Calibrators* Efavirenz, buffer, bovine serum albumin, and sodium azide	Dropper vials
	A	0.0 µg/mL 1 X 4 mL
	B	0.5 µg/mL 1 X 2 mL
	C	1.5 µg/mL 1 X 2 mL
	D	3.0 µg/mL 1 X 2 mL
	E	6.0 µg/mL 1 X 2 mL
	F	12.0 µg/mL 1 X 2 mL

*To convert results from µg/mL efavirenz to µmol/L efavirenz, multiply µg/mL by 3.168. Efavirenz levels become 1.6, 4.8, 9.5, 19.0, and 38.0 µmol/L for Calibrators B to F respectively.

4 STANDARDIZATION

There is no internationally recognized standard for efavirenz. ARK Efavirenz Calibrators are prepared by gravimetric dilution of high purity efavirenz into a synthetic proteinaceous matrix free of efavirenz.

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 ≤0.09% sodium azide.

6 INSTRUCTIONS FOR USE

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

7 PROCEDURE

Calibration

Perform a calibration using the ARK Efavirenz 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

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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