

ARK™ Methotrexate Calibrator

This ARK Diagnostics, Inc. package insert for the ARK Methotrexate 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. A Summary of Safety and Performance is available through Eudamed (European database on medical devices), SRN: US-MF-000023925.

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



EC REP

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 6827 AT Arnhem
 The Netherlands

CH REP

MedEnvoy Switzerland
 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
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Calibrator
Rx Only	For Prescription Use Only		

1 Name

ARKTM Methotrexate Calibrator

2 Intended Use

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

3 Content

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

REF	Product Description	Quantity/Volume	
5026-0002-00	ARK Methotrexate Calibrators* Methotrexate, buffer, bovine serum albumin, and preservatives	Dropper vials	
	A	0.00 µmol/L	1 X 2 mL
	B	0.05 µmol/L	1 X 2 mL
	C	0.15 µmol/L	1 X 2 mL
	D	0.25 µmol/L	1 X 2 mL
	E	0.50 µmol/L	1 X 2 mL
	F	1.20 µmol/L	1 X 2 mL

*To convert results from µmol/L Methotrexate to µg/mL Methotrexate, divide µmol/L by 2.2005. Methotrexate levels become 0.0227, 0.0682, 0.1136, 0.2272, and 0.5453 µg/mL for Calibrators B to F respectively.

4 Standardization

There is no internationally recognized standard for Methotrexate. ARK Methotrexate Calibrators are prepared by volumetric dilution of high purity, certified Methotrexate solution into a synthetic proteinaceous matrix free of Methotrexate.

5 Warnings and Precautions

- For *In Vitro* Diagnostic Use.
- Do not mix calibrators from different lot numbers.
- Use each lot as a set.

6 Instructions For Use

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

7 Procedure

Calibration

Perform a full calibration (6- point) procedure; test calibrators in duplicate. Verify the calibration curve with at least two levels of 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

ARKTM is a trademark of ARK Diagnostics, Inc.

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



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