ARK Diagnostics, Inc.

ARK™ *Methotrexate Control*

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

Customer Service

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CE 2797

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CH REP
MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

Key to Symbols Used

LOT	Batch code	YYYY-MM-DD	Use by/Expiration date
REF	Catalog Number		Manufacturer
EC REP	Authorized Representative	CE 2797	CE Mark with notified body number
IVD	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use	CONTROL	Quality Control
Rx Only	For Prescription Use Only		

Control Kit REF 5026-0003-00

1 Name

ARK™ *Methotrexate Control*

2 Intended Use

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

3 Content

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

REF	Product Description	Quality Control	Quantity/Volume
5026-0003-00 Complete Set	**ARK Methotrexate Control*** Methotrexate, buffer, bovine serum albumin, and preservatives (nominal level)	Expected Range (µmol/L)	Dropper vials
5026-0003-01 Calibration Range Controls[1]	**LOW** (0.07 µmol/L)	0.05 – 0.09	1 X 2 mL
	MID (0.40 µmol/L)	0.30 – 0.50	1 X 2 mL
	HIGH (0.80 µmol/L)	0.60 – 1.00	1 X 2 mL
5026-0003-02 High Range Controls[2]	**5** µmol/L	3.75 – 6.25	1 X 2 mL
	50 µmol/L	37.50 – 62.50	1 X 2 mL
	500 µmol/L	375.00 – 625.00	1 X 2 mL

*To convert results from µmol/L Methotrexate to µg/mL Methotrexate, divide µmol/L by 2.2005. Methotrexate levels become 0.0318, 0.1818, 0.3636, 2.272, 22.72, and 227.2 µg/mL respectively.

Each laboratory should establish its own ranges for each new lot of controls.

[1] Calibration range controls may be obtained separately as a set, REF 5026-0003-01.

[2] High range controls may be obtained separately as a set, REF 5026-0003-02.

4 Warnings and Precautions

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

5 Instructions For Use

- For a complete summary and explanation of the Methotrexate assay, refer to the package insert for the ARK Methotrexate Assay.
- Controls are ready to use. Mix each level by gentle inversion before dispensing.
- High range controls must be diluted prior to testing.
- 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.

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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