

## ARK™ Methotrexate Control

This ARK Diagnostics, Inc. package insert for the ARK Methotrexate Assay 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
	In Vitro Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Quality Control
<b>Rx Only</b>	For Prescription Use Only		

### 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
<b>5026-0003-00 Complete Set</b>	<b>ARK Methotrexate Control* (2 mL)</b> Methotrexate, buffer, bovine serum albumin, and preservatives (nominal level)	Expected Range (µmol/L)**
<b>5026-0003-01 Calibration Range Controls<sup>1</sup></b>	LOW (0.07 µmol/L)	0.05 – 0.09
	MID (0.40 µmol/L)	0.30 – 0.50
	HIGH (0.80 µmol/L)	0.60 – 1.00
<b>5026-0003-02 High Range Controls<sup>2</sup></b>	5 µmol/L	3.75 – 6.25
	50 µmol/L	37.50 – 62.50
	500 µmol/L	375.00 – 625.00

\* 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.

\*\*The ARK Methotrexate Control is a precision control. Each laboratory should establish the mean value for each control level and its own ranges for each new lot of controls.

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<sup>1</sup> Calibration range controls may be obtained separately as a set,  5026-0003-01.

<sup>2</sup> High range controls may be obtained separately as a set,  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. 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

All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

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