

## ARK Methotrexate II Control

This ARK Diagnostics, Inc. package insert for the ARK Methotrexate II 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.

### CUSTOMER SERVICE

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### KEY TO SYMBOLS USED

	Batch code	 YYYY-MM-DD	Use by/Expiration date
	Catalog Number		Manufacturer
	<i>In Vitro</i> Diagnostic Medical Device		Temperature limitation
	Consult Instructions for Use		Quality Control
<b>Rx Only</b>	For Prescription Use Only		

### 1 NAME

## ARK Methotrexate II Control

### 2 INTENDED USE

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

### 3 CONTENT


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

REF	Product Description	Quality Control	Quantity/Volume
<b>5071-0003-00</b> Complete Set	<b>ARK Methotrexate II Control*</b> Methotrexate, buffer, bovine serum albumin, and sodium azide (nominal level)	Expected Range (µmol/L)	Dropper Vials
<b>5071-0003-01</b> Calibration Range Controls <sup>1</sup>	LOW (0.070 µmol/L)	0.050 – 0.090	1 X 4 mL
	MID (0.400 µmol/L)	0.300 – 0.500	1 X 4 mL
	HIGH (0.800 µmol/L)	0.600 – 1.000	1 X 4 mL
<b>5071-0003-02</b> High Range Controls <sup>2</sup>	5 µmol/L	3.75 – 6.25	1 X 2 mL
	50 µmol/L	37.5 – 62.5	1 X 2 mL
	500 µmol/L	375 – 625	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, 2.27, 22.7, and 227 µg/mL respectively.

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

<sup>1</sup> Calibration range controls may be obtained separately as a set,

 5071-0003-01.


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

 5071-0003-02.

### 4 WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use.
- Do not mix controls from different lot numbers.
- Use each lot as a set.
- Controls contain ≤0.09% sodium azide.

### 5 INSTRUCTIONS FOR USE

- For a complete summary and explanation of the ARK Methotrexate II Assay, refer to the package insert for the ARK Methotrexate II Assay,  5071-0001-00.
- 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 at 2-8°C. Use prior to the expiration date.

### 6 LIMITATIONS OF PROCEDURE

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, controls, dilution buffer, 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.

Control Kit  5071-0003-00

Control Kit  5071-0003-01

Control Kit  5071-0003-02