

## ARK Methotrexate II Calibrator

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

### 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		Calibrator
<b>Rx Only</b>	For Prescription Use Only		

### 1 NAME

## ARK Methotrexate II Calibrator

### 2 INTENDED USE

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

### 3 CONTENT

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

REF	Product Description	Quantity/Volume
5071-0002-00	<b>ARK Methotrexate II Calibrators*</b> Methotrexate, buffer, bovine serum albumin, and sodium azide	Dropper Vials
	A	0.000 µmol/L
	B	0.050 µmol/L
	C	0.150 µmol/L
	D	0.350 µmol/L
	E	0.650 µmol/L
	F	1.300 µmol/L

\*To convert results from µmol/L methotrexate to µg/mL methotrexate, divide µmol/L by 2.2005. Methotrexate levels become 0.0227, 0.0682, 0.1591, 0.2954, and 0.5908 µg/mL for Calibrators B to F respectively.


### 4 STANDARDIZATION

There is no internationally recognized standard for methotrexate. ARK Methotrexate II Calibrators are prepared by volumetric addition of high purity, certified methotrexate 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.
- Calibrators contain ≤0.09% sodium azide.

### 6 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.
- 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.

### 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, dilution buffer, storage of product as directed, and good laboratory technique.

### 9 TRADEMARKS

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