



# ARK™ Methotrexate Dilution Buffer

This ARK Diagnostics, Inc. package insert for the ARK Methotrexate Dilution Buffer 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.

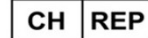
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## Key to Symbols Used

	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		Quality Control
<b>Rx Only</b>	For Prescription Use Only		

## 1 Name

**ARK<sup>TM</sup> Methotrexate Dilution Buffer**

## 2 Intended Use

ARK Methotrexate Dilution Buffer is intended for dilution of specimens containing high concentrations of methotrexate for the ARK Methotrexate Assay.

## 3 Content

ARK Methotrexate Dilution Buffer is comprised of a synthetic protein matrix. Its composition is equivalent to Calibrator A (zero), ARK Methotrexate Calibrator, **REF** 5026-0002-00.

REF	Product Description	Quantity/Volume
5026-0004-00	ARK Methotrexate Dilution Buffer Buffer, bovine serum albumin, and preservatives	1 X 25 mL

## 4 Warnings and Precautions

- For *In Vitro* Diagnostic Use.

## 5 Instructions For Use

- For a complete summary and explanation of the Methotrexate assay, refer to the package insert for the ARK Methotrexate Assay.
- Dilution Buffer is ready to use. Mix by gentle inversion before dispensing.
- Store at 2-8°C. Once opened, use within 12 months and prior to the expiration date.

## 6 Procedure – Manual Dilution Protocol

The measurement range of the ARK Methotrexate calibration curve is 0.04 - 1.20 µmol/L. Specimens and controls containing methotrexate in higher concentrations (>1.20 µmol/L), are assayed by dilution of the specimen and controls into the measurement range.

Manually dilute the high specimen or high range control with ARK Methotrexate Dilution Buffer by preparing the appropriate ten-fold serial dilution as shown below.

<b>Sample Volume</b>	<b>Dilution Matrix Volume</b>	<b>Dilution</b>	<b>Dilution Factor</b>
50 µL Undiluted sample	450 µL	1:10	10
50 µL 1:10 sample	450 µL	1:100	100
50 µL 1:100 sample	450 µL	1:1000	1000
50 µL 1:1000 sample	450 µL	1:10000	10000

$$\text{Manual Dilution Factor} = \frac{(\text{Volume of Specimen} + \text{Volume of Dilution Buffer})}{\text{Specimen Volume}}$$

Multiply the assayed result by the dilution factor. To convert µmol/L to µg/mL, divide the value obtained by the conversion factor of 2.2005.

## 7 Trademarks

ARK<sup>TM</sup> is a trademark of ARK Diagnostics, Inc.

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



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