ARK Diagnostics, Inc.

ARK *Methotrexate II Dilution Buffer*

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

Customer Service

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EC REP

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6827 AT Arnhem
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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		

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1 Name

ARK *Methotrexate II Dilution Buffer*

2 Intended Use

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

3 Content

ARK Methotrexate II Dilution Buffer is comprised of a synthetic protein matrix. Its composition is equivalent to Calibrator A (zero), ARK Methotrexate II Calibrator, REF 5071-0002-00.

REF	Product Description	Quantity/Volume
5071-0004-00	**ARK Methotrexate II Dilution Buffer** Buffer, bovine serum albumin, and sodium azide	**1 X 25 mL**

4 Warnings and Precautions

- For ***In Vitro*** **Diagnostic** Use.
- Dilution Buffer contains ≤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.
- 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 II calibration curve is 0.030 - 1.300 µmol/L. Specimens and controls containing methotrexate in higher concentrations (>1.300 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 II Dilution Buffer by preparing the appropriate ten-fold serial dilution as shown below.

Sample Volume	Dilution Matrix Volume	Dilution	Dilution Factor
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

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

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

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