

ARK™ Methotrexate Dilution Buffer

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.











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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 |
| Rx Only | For Prescription Use Only | | |


1 NAME

ARK™ 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,  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. Use prior to the expiration date. Once opened, store at 2-8°C for 12 months within the expiration date.

6 PROCEDURE – MANUAL DILUTION PROTOCOL

The measurement range of the ARK Methotrexate Assay 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.

| 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 |
| 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

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