









ARK™ SDMA Calibrator

This ARK Diagnostics, Inc. package insert for the ARK SDMA 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. The ARK SDMA Assay test system includes separately provided test kits for the ARK SDMA Assay, ARK SDMA Calibrator and ARK SDMA Control.

Customer Service

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Key to Symbols Used

| | | | |
|---|------------------------------|---|------------------------|
|  | Batch code |  YYYY- MM-DD | Use by/Expiration date |
|  | Catalog Number |  | Manufacturer |
|  | Consult Instructions for Use |  | Calibrator |
|  | Temperature limitation | | |

1 Name

ARK™ SDMA Calibrator

2 Intended Use

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

3 Content

ARK SDMA Calibrator is comprised of a synthetic protein matrix with the following concentrations of SDMA:

| REF | Product Description | | Quantity/Volume |
|--------------|---|-------------|-----------------|
| 5085-0002-00 | ARK SDMA Calibrators SDMA, buffer, bovine serum albumin, and sodium azide | | Dropper vials |
| | A | 0.0 µg/dL | 1 X 2 mL |
| | B | 7.5 µg/dL | 1 X 2 mL |
| | C | 15.0 µg/dL | 1 X 2 mL |
| | D | 30.0 µg/dL | 1 X 2 mL |
| | E | 50.0 µg/dL | 1 X 2 mL |
| | F | 100.0 µg/dL | 1 X 2 mL |

The measurement range of the ARK SDMA Assay is 4.0 – 100.0 µg/dL.

4 Standardization

There is no internationally recognized standard for SDMA. ARK SDMA Calibrators are prepared by gravimetric dilution of high purity SDMA into a synthetic proteinaceous matrix free of SDMA.

5 Warnings and Precautions

- For veterinary use only.
- 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 SDMA assay, refer to the package insert for the ARK SDMA Assay.

- Calibrators are ready to use. Mix each level by gentle inversion before dispensing.
- Squeeze sufficient volume (~40 µL/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 calibration using the ARK SDMA Calibrators A, B, C, D, E, and F. Verify the calibration curve with 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

A stored calibration curve was effective up to at least 14 days based on supporting data.

8 Limitations of Procedure

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, controls, storage of product as directed, and good laboratory technique.

All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

9 Trademarks

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



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