

## ARK<sup>L</sup> SDMA Assay

This ARK Diagnostics, Inc. package insert for the ARK SDMA 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.

### 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		Temperature limitation
 	Reagent 1/ Reagent 2		

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Reagent Kit  5085-0001-00

Reagent Kit  5085-0001-01

Reagent Kit  5085-0001-02

## 1 Name

ARK<sup>L</sup> *SDMA Assay*

## 2 Intended Use

The ARK SDMA Assay is a homogeneous immunoassay intended for the quantitative determination of SDMA in canine and feline serum. The assay is designed for use in laboratories with automated clinical chemistry analyzers.

## 3 Summary and Explanation of the Test

Symmetric dimethylarginine (SDMA) is a methylated arginine amino acid. SDMA in addition to asymmetric dimethylarginine (ADMA) and monomethylarginine (MMA) are derived from posttranslational modification (methylation) of proteins containing arginine residues within almost every cell. After proteolysis, or protein breakdown, these protein residues are released into the circulation. SDMA is eliminated from the body primarily via renal excretion. SDMA's small molecular size (molecular weight [MW], 202 g/mol)<sup>1</sup> and positive charge allow it be freely filtered by glomerular filtration. Because SDMA is largely excreted by the kidney, it is a good candidate biomarker for kidney function, whereas highly protein-bound ADMA undergoes extensive metabolism by the tissue-specific enzyme dimethylarginine dimethylaminohydrolase.<sup>2,3</sup> In a 2011 review, Schwedhelm and Böger estimated the renal excretion of SDMA to be greater than or equal to 90%, with putative cleavage of the remainder by an unnamed enzyme. In contrast, only about 20% of ADMA is excreted into the urine.<sup>4</sup> SDMA has also been shown to be a more reliable indicator of kidney function than creatinine. SDMA increases as early as 25% loss of kidney function whereas creatinine dose not increase until 75% of kidney function is lost. Unlike creatinine, SDMA is less impacted by extrarenal factors, including body condition, advanced age, and disease state<sup>5,6</sup> and is not affected by tubular reabsorption or secretion.

## 4 Principles of the Procedure

ARK SDMA Assay is a homogeneous immunoassay based on competition between drug in the specimen and SDMA labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for binding to the antibody reagent. As the latter binds antibody, enzyme activity decreases. In the presence of drug from the specimen, enzyme activity increases and is directly related to the drug concentration. Active enzyme converts the coenzyme nicotinamide adenine dinucleotide (NAD) to NADH that is measured

spectrophotometrically as a rate of change in absorbance. Endogenous serum G6PDH does not interfere with the results because the coenzyme NAD functions only with the bacterial enzyme used in the assay.

## 5 Reagents

REF	Product Description	Quantity/Volume
5085-0001-00	<b>ARK SDMA Assay</b> <b>Reagent [R1] – Antibody/Substrate</b> Rabbit monoclonal antibodies to SDMA, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, preservatives, and stabilizers	1 X 115 mL
	<b>Reagent [R2] – Enzyme</b> SDMA labeled with bacterial rG6PDH, buffer, bovine serum albumin, preservatives, and stabilizers	1 X 58 mL

REF	Product Description	Quantity/Volume
5085-0001-01	<b>ARK SDMA Assay</b> <b>Reagent [R1] – Antibody/Substrate</b> Rabbit monoclonal antibodies to SDMA, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, preservatives, and stabilizers	4 X 28 mL
	<b>Reagent [R2] – Enzyme</b> SDMA labeled with bacterial rG6PDH, buffer, bovine serum albumin, preservatives, and stabilizers	4 X 14 mL

REF	Product Description	Quantity/Volume
5085-0001-02	<b>ARK SDMA Assay</b> <b>Reagent [R1] – Antibody/Substrate</b> Rabbit monoclonal antibodies to SDMA, glucose-6-phosphate, nicotinamide adenine dinucleotide, bovine serum albumin, preservatives, and stabilizers	4 X 115 mL
	<b>Reagent [R2] – Enzyme</b> SDMA labeled with bacterial rG6PDH, buffer, bovine serum albumin, preservatives, and stabilizers	4 X 58 mL

### Reagent Handling and Storage

ARK SDMA Assay reagents are provided liquid, ready to use and may be used directly from the refrigerator. When not in use, reagents must be stored at 2–8°C (36–46°F), upright and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C (90°F). **Improper storage of reagents can affect assay performance.**

ARK SDMA products contain ≤0.09% sodium azide. As a precaution, affected plumbing including instrumentation should be flushed adequately

with water to mitigate the potential accumulation of explosive metal azides. No special handling is required regarding other assay components.

## 6 Warnings and Precautions

- For veterinary use only.
- Reagents **R1** and **R2** are provided as a matched set and should not be interchanged with reagents from different lot numbers.

## 7 Specimen Collection and Preparation for Analysis

- Serum is required.
- Whole blood cannot be used.
- Follow the collection tube manufacturer's recommendations for collection, processing and centrifugation.
- Do not induce foaming and avoid repeated freezing and thawing to preserve the integrity of the specimen from the time it is collected until the time it is assayed.
- Fibrin, red blood cells, and other particulate matter may cause an erroneous result. Ensure adequate centrifugation.
- The presence of bubbles or foam on specimens can lead to short sample delivery and erroneous results.
- Clarified specimens may be stored up to one week at 2 to 8°C. If testing will be delayed more than one week, specimens should be stored frozen ( $\leq -10^{\circ}\text{C}$ ) up to four weeks prior to being tested. Care should be taken to limit the number of freeze-thaw cycles.
- **Handle all patient specimens as if they were potentially infectious.**

## 8 Procedure

### Materials Provided

ARK SDMA Assay – **REF** 5085-0001-00, 5085-0001-01 or 5085-0001-02

### Materials Required – Provided Separately

ARK SDMA Calibrator – **REF** 5085-0002-00

Quality Controls – ARK SDMA Control – **REF** 5085-0003-00

### Instruments

Reagents **R1** and **R2** may need to be transferred to analyzer-specific reagent containers prior to use. Avoid cross-contamination of **R1** and **R2**. Many automated clinical chemistry analyzers with photometric rate determination at 340 nm are suitable. Consult the analyzer-specific application sheet for programming the ARK SDMA Assay, available from

your distributor or ARK Customer Service. Refer to the instrument-specific operator's manual for daily maintenance.

### **Assay Sequence**

To run or calibrate the assay, see the instrument-specific operator's manual.

### **Calibration**

Perform a full calibration (6-point) procedure using the ARK SDMA Calibrators A, B, C, D, E, and F; test calibrators in duplicate. Calibration is required with each new reagent kit lot number. 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

### **Quality Control (QC)**

Laboratories should establish QC procedures for the ARK SDMA Assay. All quality control requirements and testing should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Good laboratory practice suggests that at least two levels (low and high medical decision points) of quality control be tested each day patient samples are assayed and each time a calibration is performed. Monitor the control values for any trends or shifts. If any trends or shifts are detected, or if the control does not recover within the specified range, review all operating parameters according to your clinical laboratory quality procedures. Contact Customer Service for further assistance.

### **Manual Dilution Protocol**

To estimate SDMA levels in specimens exceeding the upper limit of quantitation, manually dilute the specimen with zero calibrator (CAL A). Multiply the assayed result by the dilution factor.

$$\text{Manual Dilution Factor} = \frac{\text{Volume of Specimen} + \text{Volume of CAL A}}{\text{Volume of Specimen}}$$

## **9 Results**

Report result units as µg/dL.

## 10 Limitations of Procedure

This assay is designed for use with serum only; refer to the section **Specimen Collection and Preparation for Analysis**. It is generally good practice to use the same method (as well as matrix) consistently for individual patient care due to the potential for method-to-method variabilities. See the section **Expected Values** below.

## 11 Expected Values

It is highly recommended that each laboratory establishes its own decision limits. If a lab is not able to establish its own reference range, the following ranges can be used based on recent publications<sup>8</sup>:

Normal range dog: < 15 µg/dL

Normal range puppy dog: < 17 µg/dL

Normal range cat: < 14 µg/dL

## 12 Specific Performance Characteristics

Each laboratory is responsible for verification of performance using instrument parameters established for their analyzer.

### **Sensitivity**

#### Limit of Quantitation (LOQ)

The LOQ of the ARK SDMA Assay was determined according to CLSI EP17-A and is defined as the lowest concentration for which acceptable inter-assay precision and recovery is observed ( $\leq 20\%$  CV with  $\pm 15\%$  recovery). The LOQ was determined to be 4.0 µg/dL, and may depend on analyzer-specific performance.

### **Assay Range**

The range of the assay is 4.0 to 100.0 µg/dL. Report results below this range as <4.0 µg/dL or below the analyzer-specific lower LOQ established in your laboratory. Report results above this range as >100.0 µg/dL or above the analyzer-specific upper LOQ established in your laboratory.

### **Linearity and Recovery**

Linearity and accuracy (analytical recovery) studies were performed as suggested in CLSI Protocol EP6-A. A 100.0 µg/dL serum sample was

prepared and dilutions were made proportionally with human serum negative for SDMA. SDMA concentrations ranged from 2.5 to 100.0 µg/dL. Linearity at specific dilutions was considered acceptable if the percent difference was ±10% between the predicted 1<sup>st</sup> and 2<sup>nd</sup> order regressed values or ±0.75 µg/dL below 7.5 µg/dL. A linear relationship was demonstrated between 2.5 and 100.0 µg/dL. Results are shown below.

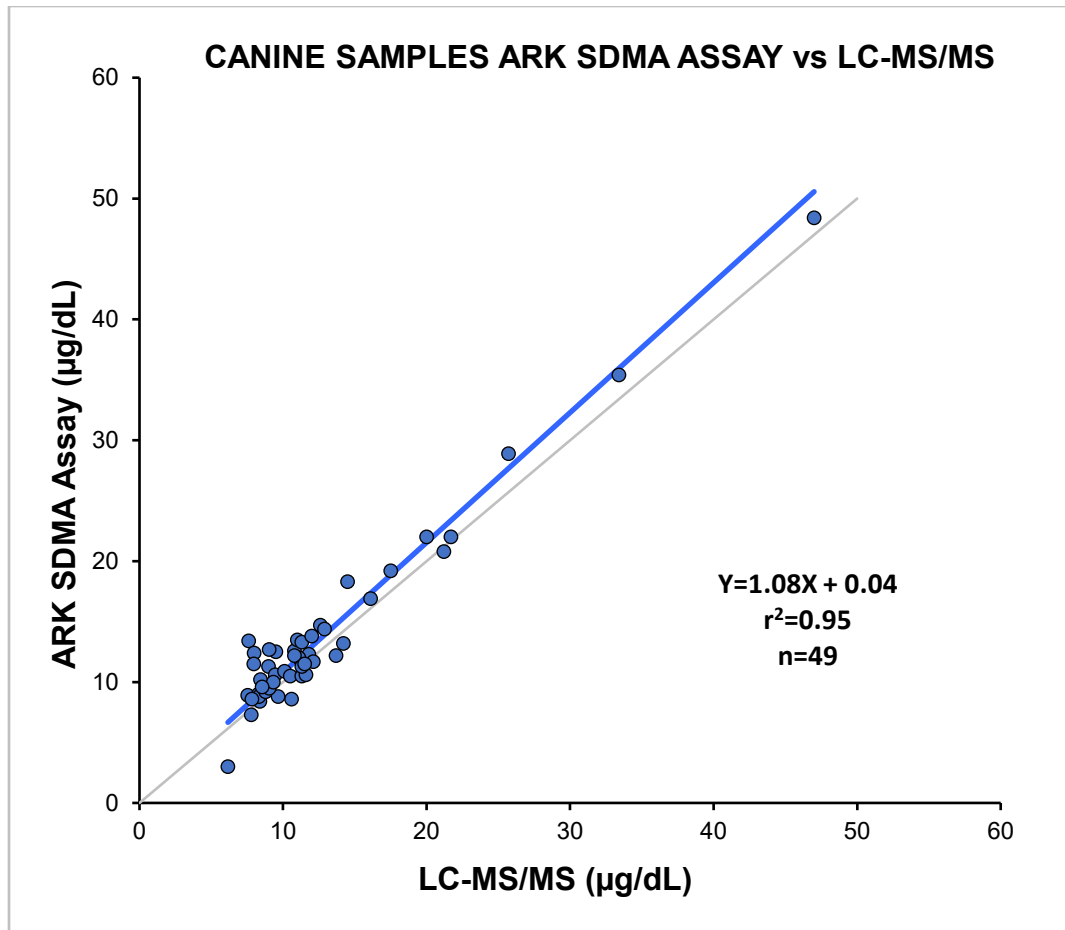
<b>Estimated Value (µg/dL)</b>	<b>Results (µg/dL)</b>	<b>% Recovery</b>	<b>1st Order Predicted Results</b>	<b>2nd Order Predicted Results</b>	<b>% Difference</b>
0.0	0.6	NA	0.4	0.1	NA
2.5	2.6	104.0	2.9	2.7	-8.5
5.0	5.2	104.7	5.4	5.2	-3.3
10.0	10.1	100.5	10.4	10.4	-0.5
20.0	20.3	101.5	20.4	20.6	0.8
30.0	30.5	101.6	30.4	30.8	1.1
50.0	51.7	103.4	50.4	50.9	0.9
70.0	70.6	100.9	70.4	70.8	0.5
90.0	91.5	101.6	90.5	90.5	0.0
100.0	98.4	98.4	100.5	100.2	-0.3

### **Method Comparison**

Correlation studies were performed using CLSI Protocol EP9-A2. Results from the ARK SDMA Assay were compared with results from LC-MS/MS for canine and feline specimens.

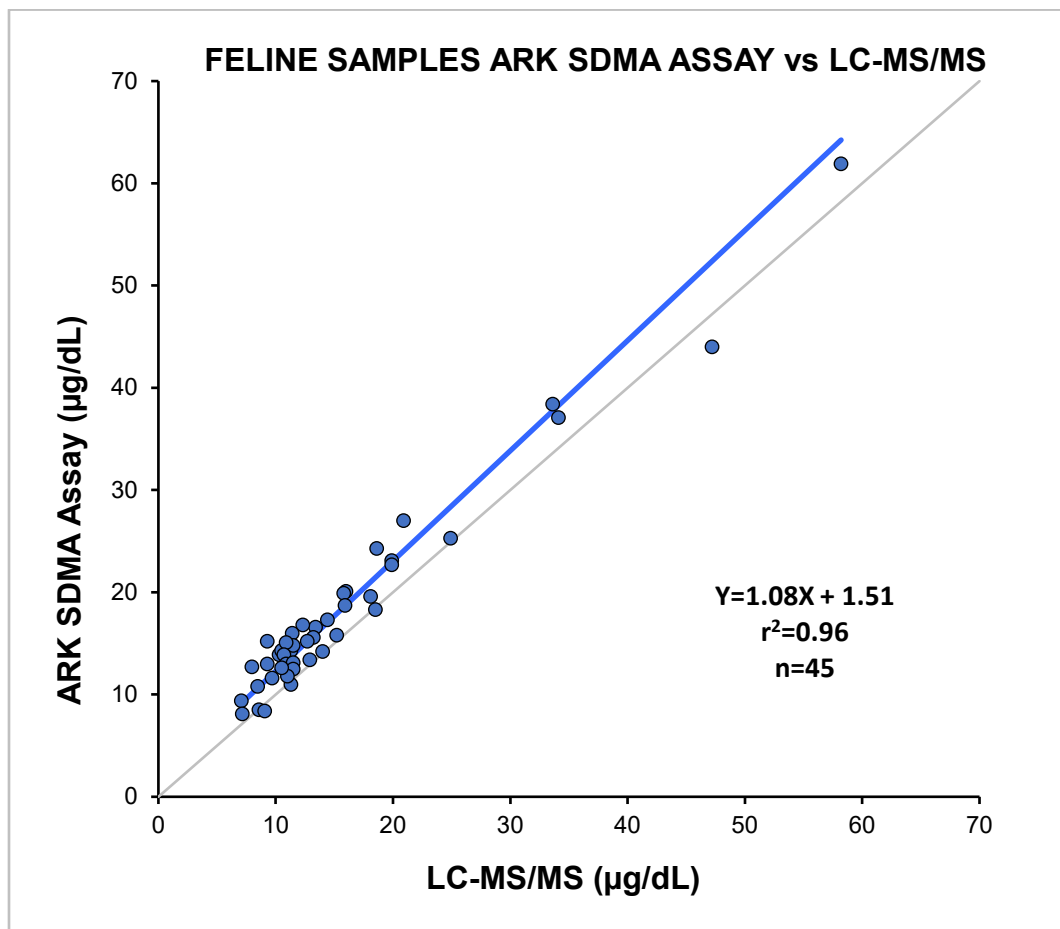
Results of the Passing-Bablok<sup>16</sup> regression analysis for the canine study are shown below.

Slope	1.08
y-intercept	0.04
Correlation Coefficient (r <sup>2</sup> )	0.95
Number of Samples	49



Results of the Passing-Bablok<sup>16</sup> regression analysis for the feline study are shown below.

Slope	1.08
y-intercept	1.51
Correlation Coefficient ( $r^2$ )	0.96
Number of Samples	45



### Precision

Precision was determined as described in CLSI Protocol EP5-A2. Quad-level controls containing SDMA were used in the study. Each level was assayed in quadruplicate twice a day for 5 days. Each of the runs per day was separated by at least two hours. The within run, between day, total SD, and percent CVs were calculated. Results are shown below. Acceptance criteria: <10% total CV.

Sample (µg/dL)	N	Mean (µg/dL)	Within Run		Between Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
10	40	10.6	0.63	6.3	0.47	4.4	0.72	7.2
14	40	14.2	0.75	5.3	0.46	3.3	0.82	5.8
20	40	20.5	0.57	2.9	0.65	3.2	0.88	4.4
60	40	60.9	1.60	2.7	1.39	2.3	1.97	3.3

### Interfering Substances

Interference studies were conducted using CLSI Protocol EP7-A3 as a guideline. High concentrations of the following potentially interfering substances with known levels of SDMA (approximately 14 µg/dL) were evaluated. Each sample was assayed using the ARK SDMA Assay. Measurement of SDMA resulted in ≤15% error in the presence of interfering substances at the levels tested.

Interfering Substance	Interferent Concentration	Percentage Recovery
Bilirubin	70 mg/dL	97.6
Cholesterol	500 mg/dL	86.4
Hemoglobin	1000 mg/dL	110.2
Triglycerides	500 mg/dL	94.8
Uric Acid	30 mg/dL	93.3

### Specificity

ADMA, L-Arginine, MMA, and Symmetric N $\alpha$ -acetyl-dimethylarginine were prepared at 1000  $\mu\text{g}/\text{dL}$ . Each sample was tested in triplicate. Percent cross-reactivity ranged from 0.1 to 4.7%.

Compound	Concentration Tested ( $\mu\text{g}/\text{dL}$ )	Mean ( $\mu\text{g}/\text{dL}$ )	Percent Cross-Reactivity
ADMA	1000	3.6	0.4
L-Arginine	1000	0.8	0.1
MMA	1000	46.8	4.7
N $\alpha$ -acetyl-dimethylarginine	1000	29.8	3.0

## 13 References

### REFERENCES

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## 14 Trademarks

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