Element i+ SDMA Cartridge Instructions

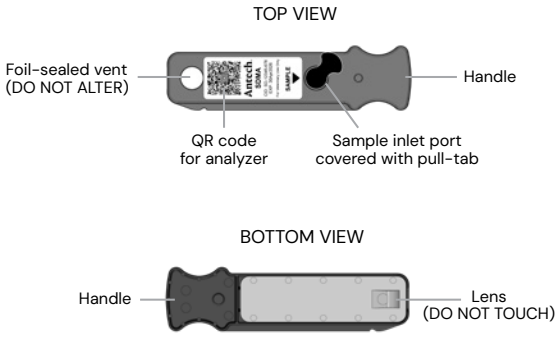
Intended Use

The Element i+™ SDMA assay is an in vitro diagnostic test for the quantitative determination of SDMA in canine or feline serum or lithium heparin plasma. SDMA (Symmetric Dimethylarginine) is intended for use as a biomarker to assess renal function in both feline and canine patients. It aids in the early detection of kidney disease, monitoring of disease progression, and evaluation of treatment response.

Clinical Ranges

LEVEL	INTERPRETATION
≤ 14.0 µg/dL	Normal
14.1-19.9 ug/dL	Mild increase
≥ 20.0 µg/dL	High

Element i+ Cartridge Description



Principle of the Measurement

The Element i+ SDMA test uses a competitive immunoassay to generate a quantitative SDMA concentration output. When a specimen is added to a cartridge inlet port, it is mixed with a dried fluorophore-labeled anti-SDMA antibody. The mixture then reacts with SDMA immobilized on the cartridge sensor surface. SDMA in the sample competes with SDMA on the surface for binding to the fluorophore-labeled anti-SDMA antibody. Fluorescence illumination is by diode laser light coupled into the lens of the proprietary planar waveguide cartridge. Fluorescence imaging is used for signal transduction.
The fluorescence generated is inversely proportional to the SDMA concentration of the specimen. Fluorescence intensity is converted to a quantitative SDMA concentration using cartridge lot-specific calibration information.

Warnings

⚠ Do not touch the clear bottom of the cartridge.
⚠ Do not alter the silver foil seal on top of the cartridge. Do not use a cartridge with a punctured silver seal.
⚠ Do not use a cartridge dropped on the floor.
⚠ A new cartridge must be used for each measurement. The Element i+ Immunodiagnostic Analyzer will not allow a cartridge to be used more than one time.
⚠ Used cartridges should be disposed of as biohazard waste in accordance with local laws.

Additional Equipment

- Element i+ Immunodiagnostic Analyzer
- 100 microliter fixed volume mini-pipette (supplied with analyzer and available separately)
- Pipette tips (supplied with analyzer and available separately)

Specimen Requirements

The test has been designed to be run with fresh canine or feline serum or lithium heparin plasma samples. Other plasma sample types have not been tested.

- Avoid using plasma or serum with precipitates.
- Do not dilute the sample.

Running a Test

1. Obtain a serum or lithium heparinized plasma sample.
2. On the main screen of the analyzer, touch Worklist or Manual Test.
   - In Worklist Mode, confirm that all fields have correct information and then touch ✓ to proceed.
   - In Manual Mode, enter sample information in the required fields.
   - Touch ✓ to proceed.
3. Open the pouch by tearing at the notch. Carefully remove the cartridge by the handle and place it on a flat surface.
   Note: Do not touch the bottom of the cartridge.
   Note: If the cartridge was refrigerated, allow to warm to room temperature for at least 15 minutes before opening the pouch.
   Note: Cartridge must be used within 1 hour of removal from pouch.
4. With the cartridge flat on the bench, remove the pull-tab from the sample inlet port and discard. Use the cartridge handle to steady the flat cartridge while removing the pull-tab.
   Note: Cartridge must be used within 15 minutes of removing pull-tab.
5. Affix a tip to the 100 µL fixed volume mini-pipette. Aspirate 100 µL of sample, insert the pipette tip into the inlet port hole, and dispense the full sample amount into the hole.

6. Touch on the Prepare Sample screen to open the analyzer door.
   - Insert the cartridge until you feel a click and hear a beep.
7. The test will run automatically. A status bar and countdown timer will display on the screen and the indicator light on the front of the analyzer will blink to indicate a test is running: To cancel during the run, touch X at the upper right of the screen.
8. Upon test completion, patient results will display on the screen.
   - Touch (home button) to exit results screen.
   - The screen will provide an indication when it is safe to remove the used cartridge.

   Note: Do not attempt to remove cartridge before signaled by the analyzer.

Performance Characteristics

Reporting range: 7.0 to 80.0 µg/dL

Accuracy:
The assay demonstrates a Passing–Bablok regression slope of 1.00 ± 0.20 (95% confidence interval) when compared to the designated reference method for samples within the range of 7.0–80 µg/dL.

Precision:
- Coefficient of Variation ≤5% for samples 7.0-30.0 µg/dL SDMA
- Coefficient of Variation ≤ 11% for samples >30.0 µg/dL SDMA

Known Interfering Substances

INTERFERENCE	INTERFERING SUBSTANCE AND CONDITIONS TESTED	SDMA SAMPLE CONCENTRATIONS TESTED	RESULT
Protein	Up to 7g/dL	15 µg/dL and >20 µg/dL	No significant effect
Icterus	Bilirubin up to 35 mg/dL		
Hyperlipidemia	Up to 600 mg/dL		
Hemolysis	Hemoglobin up to 1 g/dL		
Lipemia	Triglycerides up to 1000 mg/dL		

Storage and Shelf Life

- Storage: 35.6–77 °F (2–25 °C)
- Expiration date: Printed on the cartridge pouch

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