SDMA on the Element i+ Product Bulletin

Introduction

Symmetric Dimethylarginine (SDMA) is a methylated derivative of arginine produced during normal protein turnover and eliminated almost exclusively by the kidneys. As a renal biomarker, SDMA reflects Glomerular Filtration Rate (GFR) in dogs and cats. Unlike direct GFR measurement, which is costly and impractical in clinical practice, SDMA can be measured from a single blood sample, providing a practical and efficient tool for assessing kidney health. Antech has long provided SDMA through its reference laboratories, ensuring broad access; SDMA onto the Element i+™ brings the same analyte in-hospital for faster, same-visit assessment without compromising alignment to reference-lab staging cutoffs. This advancement enables veterinarians to make timely decisions for early detection, staging, and monitoring of kidney disease in dogs and cats—improving patient outcomes and client compliance.

Assay Overview

Intended use: Quantitative determination of SDMA in canine/feline serum or lithium heparin plasma.

Reportable range: 7.0– 80.0 µg/dL.

Materials and Methods

A method-comparison study followed CLSI EP09c for measurement procedure comparison and bias estimation using patient samples. Statistical analyses included regression (Passing–Bablok/Deming). The Antech reference laboratory SDMA immunoassay on a Beckman AU served as the comparative procedure. Feline (177) and canine (188) samples spanning the reportable range 7–80 µg/dL were tested on both reference method and Element i+.

Precision study was executed with 15×2×3 (15 days, two runs/day, three replicates/run) format to determine repeatability and within-laboratory precision. A reproducibility study was conducted with 5×5×3 (five days, five replicates, three instruments) to estimate repeatability and between-laboratory reproducibility. The study designs were based on CLSI EP05-A3.

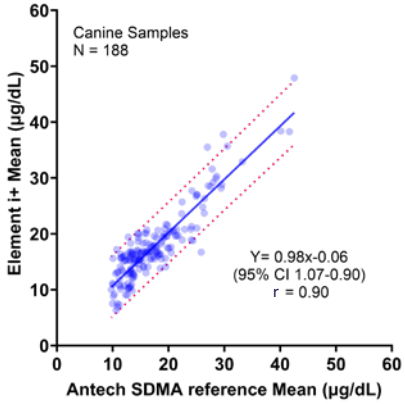
Interference testing was completed to determine the effect of five common endogenous substances on test results. A cross-reactivity study looked at several analytes on SDMA measurement using the Element i+ assay, following CLSI EP07 principles.

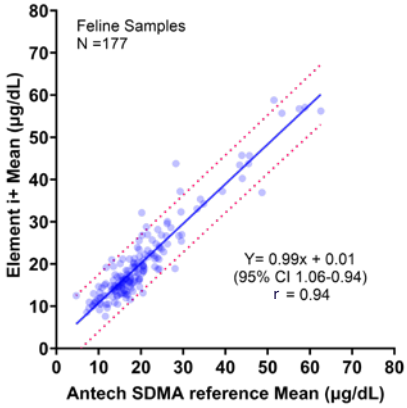
Results

Method Comparison: Overall bias <20% within 95% CI for samples ≥7.0 µg/dL. Excellent correlation with Antech reference method (Canine slope ≈0.98; Feline slope ≈0.99). Additional analysis was completed, focused on samples near the clinical decision points (14-20 µg/dL). Bland Altman analysis shows mean bias for canines -0.14 µg/dL

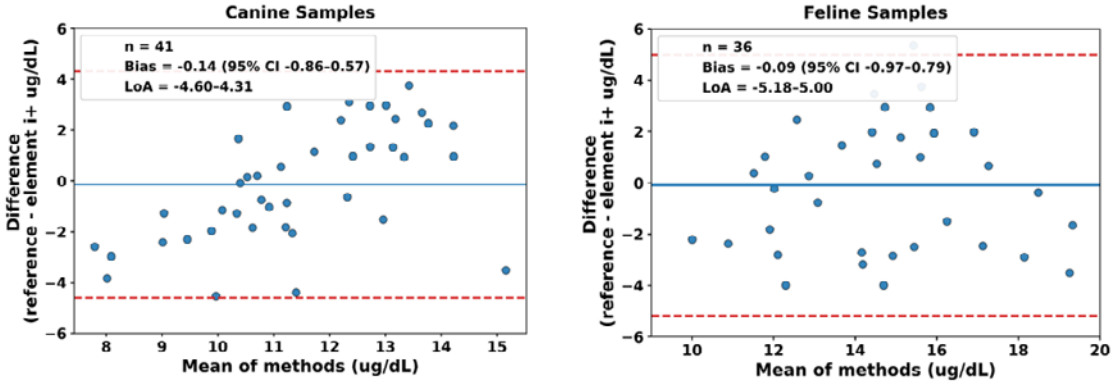
Limits of agreement: Canine (-4.6 to +4.3 µg/dL) and for feline -0.09 limit of agreement (-5.1 to +5.0 µg/dL). Supports use of common interpretive cut-points (≤14.0, 14.1–19.9, ≥20.0 µg/dL).

Regression Plots





Bland Altman Plots



Precision: CV ≤5% for 7–30 µg/dL; and ≤11% for >30 µg/dL.

Reproducibility: CV ≤10% 7–30 µg/dL and ≤15% >30 µg/dL.

Interference: No clinically significant effect from protein (7 g/dL), bilirubin (35 mg/dL), cholesterol (600 mg/dL), hemoglobin (1 g/dL), or triglycerides (1,000 mg/dL).

Cross-reactivity: Tested against ADMA, MMA, and L-arginine; all ≤2%change, no clinically significant effect.

Conclusion

The Element i+ SDMA assay provides a robust in-hospital complement to reference-lab testing, with validated performance across accuracy, precision, interference, and specificity studies. Combined with SDMA's recognized clinical utility, this enables same-visit renal assessment and improved patient care.