Vcheck

SDMA 2.0

CANINE & FELINE SDMA

For veterinary use only

INTENDED USE

The Vcheck SDMA 2.0 is an *in vitro* diagnostic test kit for the quantitative measurement of SDMA concentration in canine or feline serum and plasma. Symmetric dimethylarginine (SDMA) is a methylated derivative of arginine produced from intranuclear methylation of L-arginine residues. SDMA is primarily excreted by the kidneys, making it an endogenous marker of renal function. SDMA is a more reliable indicator of kidney function than creatinine and the measurement of SDMA can be used to detect both acute kidney injury (AKI) and chronic kidney disease (CKD) earlier than ever. The BIONOTE Vcheck SDMA 2.0 is designed to be used only by veterinarians.

PRINCIPLE

The product utilizes a competitive immunoassay employing a mouse monoclonal anti-SDMA antibody that specifically binds to SDMA. The sample is first diluted with an assay diluent and mixed with a tablet containing fluorescent particles conjugated with the antibody to form a sample mixture. When the mixture is applied to the sample hole of the Vcheck SDMA 2.0 test device, it moves along the internal membrane by capillary action. If SDMA antigen is present, it competes with the SDMA pre-coated on the test line for binding to the europium-labeled antibodies, resulting in a weaker fluorescence signal at higher SDMA concentrations. In the absence of SDMA antigen, the labeled antibodies bind to the coated SDMA, producing a stronger signal. Fluorescence is detected by the optical system in the BIONOTE Vcheck analyzer, which calculates and displays the SDMA concentration using an internal algorithm.

MATERIALS PROVIDED

Reagent	5 Tests/Kit	10 Tests/Kit	20 Tests/Kit
① Vcheck SDMA 2.0 Test device	5	10	20
② Assay diluent tube	5	10	20
③ Disposable tablet pipette (orange bulb)	5	10	20
④ Disposable pipette tip	10	20	40
⑤ Instructions for use	1	1	1

MATERIALS REQUIRED, BUT NOT PROVIDED

1. BIONOTE Vcheck analyzer
2. Sample collection tube
3. Pipette
4. Sterilized syringe

STORAGE AND STABILITY

1. Store the test kit at 2–8 °C. **DO NOT FREEZE.**
2. Do not store the test kit in the direct sunlight.
3. The test kit is stable until the expiry date that is marked on the package label.

Reagent	Open status	Storage	Stability	Note
Test device	Unopened	2–8 °C, Sealed	9 months	Finished product
	Opened	Do not store	-	Use directly
Tablet pipette	Unopened	2–8 °C, Sealed	9 months	Finished product
	Opened	Do not store	-	Use directly
Assay diluent	Unopened	2–8 °C, Sealed	9 months	Finished product
	Opened	Do not store	-	Use directly

*** Do not freeze the test kit.**

PRECAUTIONS

1. The test kit is for canine or feline use only. Do not use for other animals.
2. This reagent needs to be stored at 2–8 °C (**DO NOT FREEZE**). Keep the test device away from direct sunlight.
3. If refrigerated, allow all kit components to reach room temperature (15–30 °C) prior to testing.
4. Severely hemolyzed, hyperlipidemic, or hyperbilirubinemic samples may affect test results and are therefore not recommended for use.
5. Please use the recommended tubes for sample preparation. Failure to do so may adversely affect test performance and/or produce invalid results.
6. Strictly follow the test procedure (e.g. adequate sample volume), as failure to do so may adversely affect test performance and/or produce invalid results.
7. Although the Vcheck SDMA 2.0 Test Kit offers simple and quick quantitative measurement of SDMA concentration in canine or feline serum and plasma, there may be a difference in the detection performance with other clinical or laboratory methods with more sophisticated principles.
8. Do not use the test kit beyond the stated expiry date marked on the label.
9. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
10. Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.
11. Professional veterinarian should make a final diagnosis based on the results of this product, other test results and clinical findings.
12. BIONOTE Vcheck analyzer is recommended to use at 15–30 °C.

COLLECTION AND PREPARATION OF SAMPLE

1. Serum or plasma of both canine and feline should be used with this test. A method for preparing the sample is as follows.
2. **[Serum]** Collect blood using a serum collection tube (without anticoagulant). Leave to settle for at least 30 minutes for blood coagulation and then centrifuge to obtain the serum supernatant.
   [Plasma] Collect blood into a blood collection tube containing anticoagulant (**ONLY HEPARIN**) and then centrifuge to obtain plasma supernatant.
3. If separated serum or plasma samples are stored at room temperature (15–30 °C), they should be used within 6 hours. When refrigerated at 2–8 °C, they should be used within 1 week. For longer storage, samples can be frozen (-20 °C or colder) and used within 2 months.

TEST PREPARATION

1. Allow all kit components and samples to reach room temperature (15–30 °C) prior to testing.
2. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the aluminum foil pouch.
3. Do not touch the membrane in the result window of the test device.
4. Do not use the test kit if the aluminum foil pouch is damaged.
5. Do not mix components from different lot numbers, the components in this kit have been quality control tested as a standard batch unit.
6. Prepare the necessary kit components by referring to the '**MATERIALS PROVIDED**' section.

*** Leave refrigerated or frozen samples at room temperature (15–30 °C) before use.**

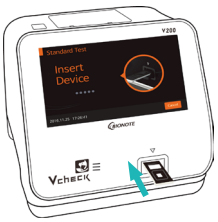
TEST PROCEDURE

Allow all kit components and samples to reach room temperature (15–30 °C) for at least 30 minutes prior to testing.

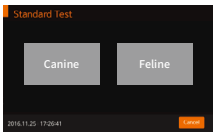
[Coding]

① Turn on V200 analyzer and select "Standard Test".

② Remove the test device from the aluminum foil pouch. Once the "Insert Device" is displayed in the screen, insert the test device.

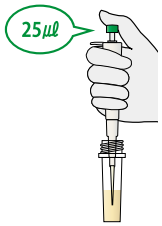


③ Select the species of the sample to be tested by choosing either the "Canine" or "Feline" button.



[Dilution of sample & Measurement]

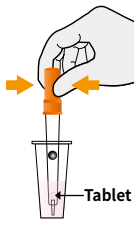
④ Draw 25 µℓ of sample using 25 µℓ pipette and add the sample into an assay diluent tube.



⑤ Using the tablet pipette, mix at least 8 times to ensure that the light purple tablet inside is fully dissolved.

*** Before using the tablet pipette, gently tap it to allow the tablet to settle at the bottom.**

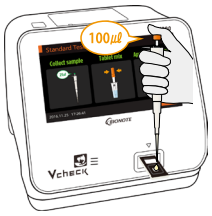
*** Squeeze the orange bulb slowly while pipetting to minimize air bubble formation.**



Orange bulb

⑥ Draw 100 µℓ of mixed sample using a 100 µℓ pipette and add into the sample hole of the test device. Then, press [START] to initiate testing.

*** Caution: If the time to press [START] button is delayed, it may affect the test result.**



⑦ The V200 analyzer will display the test result on the screen after 10 minutes.

⑧ Remove the test device.

INTERPRETATION OF THE RESULT

1. Read the concentration value of canine or feline SDMA appearing on the display of the BIONOTE Vcheck analyzer. (10 – 100 µg/dL)
2. If "↓ 10 µg/dL" appears on the display, it means the concentration of SDMA in the sample is less than 10 µg/dL.
3. If "↑ 100 µg/dL" appears on the display, it means the concentration of SDMA in the sample is greater than 100 µg/dL.
4. If the [Invalid] result appears on the screen, a retest shall be carried out.

REFERENCE RANGE

≤ 14 µg/dL	14.1 – 19.9 µg/dL	≥ 20 µg/dL
Normal (≤ 16 µg/dL in puppies*)	Gray zone (Check other evidence of kidney disease)	Abnormal (Kidney disease probable)

*** Mildly increased SDMA concentrations (14–16 µg/dL) in puppies should be interpreted in light of the growth phase as well as other evidence of kidney disease.**

PERFORMANCE CHARACTERISTIC

1. Measuring Range
   The measurable range for canine and feline SDMA is 10–100 µg/dL. For results exceeding 100 µg/dL, the sample may be diluted with a negative sample and remeasured to obtain a numerical value. To calculate the final concentration of sample, multiply the measured result by the dilution factor.
2. Interference study
   No interference was observed for each substance up to the concentration presented in the following table.

[Canine and Feline]

Interfering substances	Concentration
Cholesterol	500 mg/dL
Triglyceride	1,000 mg/dL
Bilirubin	10 mg/dL
Vitamin C	100 mg/dL
Hemoglobin	500 mg/dL
Heparin	180 Unit/mL
EDTA	5.4 mg/mL

SCREEN MESSAGES AND TROUBLE SHOOTING

[V200]

Error message	Error description
Contaminated Device	The test device is damaged or inserted improperly. **Solution:** Discard the test device and retest with a new test device and a new sample.
Insufficient Sample	An insufficient amount of blood has been applied. **Solution:** Retest with a new test device with enough sample, ensuring that blood is placed in to the narrow channel in the top edge of the test device.
Expired Device	The test devices are expired. **Solution:** Retest with a new test device that is not expired.
Temperature Error	The environmental temperature is above or below the operating range of the analyzer. **Solution:** Move to an area in the acceptable temperature range for the analyzer and perform the test. Do not heat or cool the analyzer artificially.
Printer Connection Fail	The communication between analyzer and barcode or printer has failed. **Solution:** Reconnect the analyzer and external device. If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Barcode Error	
Extremely High Total Hemoglobin	The measured total hemoglobin is out of the range of 7 to 23 g/dL. **Solution:** This error occurs when a sample has a total hemoglobin in the abnormal range. If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Result: Invalid	The test is invalid. **Solution:** Retest with a new test device and a new patient sample. If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Calibration Overdue	The calibration is overdue. **Solution:** If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.
Not Supported Device	A test device that is not supported by the analyzer has been loaded. **Solution:** Check whether the test device is manufactured by BIONOTE, Inc.
EEE	Internal error has occurred. **Solution:** If the error continues after turning ON/OFF the analyzer, please contact BIONOTE, Inc.

Doc. No. : IF147-0E
Issued date : May. 15, 2025

BIONOTE, Inc.
22, Samsung 1-ro 4-gil, Hwaseong-si, Gyeonggi-do,18449, Republic of Korea
TEL: 82-31-211-0516 I FAX : 82-31-8003-0618 I www.bionote.co.kr