Vcheck

Canine TnI

CANINE TROPONIN I

For veterinary use only

INTENDED USE

The Vcheck Canine TnI is an *in vitro* diagnostic test kit for the quantitative measurement of cardiac troponin I concentration in canine serum. Troponins are part of the contractile apparatus of cardiac muscle tissue. The troponin complex consists of 3 different proteins (troponin T, C, and I). Of the troponins, cardiac troponin I (TnI) is most specific for cardiac myocyte injury. Cardiac injury leads to the release of cardiac TnI into circulation, where its concentration correlates with the degree of cardiac damage. The BIONOTE Vcheck Canine TnI is designed to be used only by veterinarians.

PRINCIPLE

The Vcheck Canine TnI Test Kit is a fluorescent immunoassay for the quantitative measurement of Canine TnI concentration.
The Vcheck Canine TnI Test Kit uses specific Canine TnI antibodies that bind to Canine TnI. The test procedure involves dissolving fluorescent microparticles conjugated to these specific antibodies into assay diluent that reacts with Canine TnI in the sample. When the sample is applied to the sample hole of the test device, Canine TnI in the sample migrates along the nitrocellulose membrane and forms complexes with the anti-Canine TnI antibodies coated on the membrane. As a result, the density of the test line reflects the concentration of Canine TnI in the sample. The BIONOTE Vcheck Analyzer reads the density of this test line and calculates the Canine TnI concentration from the calibration curve data. The control line is a reference line that indicates whether the test has been performed correctly.

MATERIALS PROVIDED

Reagent	5 Tests/Kit
① Vcheck Canine TnI Test device	5
② Assay diluent tube	5
③ Disposable pipette tip	5
④ Instructions for use	1

MATERIALS REQUIRED, BUT NOT PROVIDED

1. BIONOTE Vcheck Analyzer
2. 100 µℓ pipette

STORAGE AND STABILITY

1. Store the test kit at 1~30°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.

PRECAUTIONS

1. The test kit is for canine use only. Do not use for other animals.
2. The test device is sensitive to humidity and heat. Perform the test immediately after removing the test device from the foil pouch.
3. Do not reuse test components.
4. Do not touch the membrane in the result window of the test device.
5. Do not use the test kit beyond the stated expiry date marked on the label.
6. Do not use the test kit if the pouch is damaged or the seal is broken.
7. Do not mix components from different lot numbers, the components in this kit have been quality control tested as a standard batch unit.
8. All samples should be handled as being potentially infectious. Wear protective gloves while handling samples. Wash hands thoroughly afterwards.
9. Decontaminate and dispose of all samples, used kits and potentially contaminated materials safely in accordance with national and local regulations.

COLLECTION AND PREPARATION OF SAMPLE

1. Canine serum should be used with this test.
2. **[Serum]** Collect the whole blood into a blood collection tube that does not contain anticoagulant. Then centrifuge to get a serum supernatant.
3. It is recommended to immediately use the separated serum and to perform the test within an hour of sample collection. If samples are not tested immediately, they can be stored frozen at -20°C or below for up to 2 months.
   Frozen samples should be brought to room temperature (15~30° C) prior to use. Samples that have been repeatedly frozen and thawed cannot be used.
   * Serum samples stored frozen at -20°C or below must be completely thawed and should be mixed via vortexing or pipetting before use.

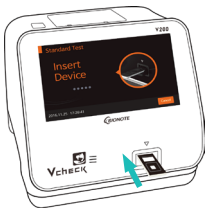
TEST PROCEDURE

Allow all kit components and sample to reach room temperature (15~30°C) prior to testing.

[Coding]

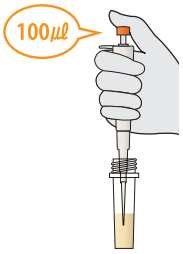
1. Turn on V200 Analyzer and select “Standard Test".

2. Remove the test device from the foil pouch. Once the “Insert device” is displayed in the screen, insert the test device.

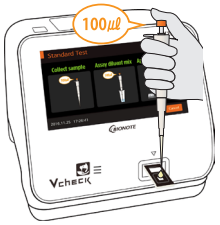


[Dilution of sample & Measurement of TnI value]

1. Using a 100 µℓ pipette, draw 100 µℓ of sample (serum) and add the sample into an assay diluent tube. And then, mix the sample with diluent by pipetting for 5~6 times.



2. Add the mixed sample (100 µℓ) into the sample hole of the test device and press the [START] button to initiate testing.
   * If the time to press [START] button is delayed, it may affect the test result.



3. The V200 analyzer will display the test result on the screen after 10 minutes.
4. Remove the test device.

INTERPRETATION OF THE RESULT

1. Read the concentration value of Canine TnI appearing on the display of the BIONOTE Vcheck Analyzer. (0.01 ~ 20 ng/ml)
2. If "< 0.01 ng/ml" appears on the display, it means the concentration of Canine TnI the specimen is less than 0.01 ng/ml.
3. If "> 20 ng/ml" appears on the display, it means the concentration of Canine TnI the specimen is greater than 20 ng/ml.

REFERENCE RANGE

< 0.03 ng/ml	0.03 - 0.12 ng/ml	> 0.12 ng/ml
Normal	Suspected	Abnormal

* TnI concentrations should not be used to either confirm or exclude primary cardiac disease without the simultaneous use of echocardiography.

** When interpreting a slight increase of TnI in healthy dogs, biological variation of TnI or old ages should be taken into account.

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 specimen.
Insufficient Sample	An insufficient amount of blood has been applied. **Solution:** Retest with a new test device with enough specimen, 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 specimen 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 specimen. 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	Loading a test device that is not supported by the analyzer. **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.

PERFORMANCE CHARACTERISTIC

1. Measuring Range
   Canine TnI concentration can be measured within the range of 0.01~20 ng/ml by using a serum. To get numerical results for > 20 ng/ml concentration ranges, samples need to be diluted with negative serum and measured again. To calculate the final Canine TnI concentration, the measured result must be multiplied by the dilution factor.
2. Interference
   Clinically, Vcheck Canine TnI concentrations are not significantly affected by hemolysis, lipemia, and icterus, as shown in the table below.

Interfering substances	Concentration
Hemoglobin	< 150 mg/dL
Intralipid	< 2,500 mg/dL
Cholesterol	< 250 mg/dL
Bilirubin	< 20 mg/dL
Vitamin C	< 1 mg/ml

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