



Vcheck cPL

For veterinary use only

[Intended Use]

The BIONOTE Vcheck cPL is an *in vitro* diagnostic test kit for the quantitative measurement of canine pancreas-specific lipase concentration in canine serum. Since the kit provides quantitative measurement of canine serum pancreas-specific lipase levels, BIONOTE Vcheck cPL can be tested with every dog presenting vomiting, anorexia or abdominal pain to diagnose pancreatitis. The BIONOTE Vcheck cPL is designed to be used only by veterinarians.

[Principle]

The Vcheck cPL Test kit is a fluorescent immunoassay for the quantitative measurement of canine pancreas-specific lipase concentration. The Vcheck cPL Test kit uses specific anti-cPL antibodies that bind to cPL. The test proceeds by dissolving fluorescence micro particles conjugated to these specific antibodies into assay diluent that react with cPL in the sample. When this specimen is applied to the sample hole of the test device, cPL in the specimen migrates along the nitrocellulose membrane and forms complexes with the anti-cPL antibodies coated on the membrane. As a result, the density of the test line reflects the concentration of canine pancreas-specific lipase in the canine serum. The BIONOTE Vcheck Analyzer reads the density of this test line and calculates the canine pancreas-specific lipase concentration from the calibration curve data. The control line is a reference line which indicates the test has been performed correctly.

[Materials provided]

Reagent	10 Tests/Kit
① Vcheck cPL Test device	10
② Assay diluent tube	10
③ Disposable tablet sput (orange bulb)	10
④ Disposable capillary tube	10
⑤ Instructions for use	1

[Materials required, but not provided]

BIONOTE Vcheck Analyzer

[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 expiration date that 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 expiration 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 containing NO anticoagulant. Leave to settle for 30 minutes for blood coagulation and then centrifuge to get a serum supernatant.
3. If serum samples are not tested immediately, they should be refrigerated at 2~8°C and used within 2 weeks. For longer storage, freeze at -20°C or below and use within 1 year. Frozen samples should be brought to room temperature (15~30°C) prior to use.

[Test procedure]

All reagents and samples must be at room temperature(15~30°C) before use.

[Coding]

1. Turn on BIONOTE Vcheck Analyzer and enter "Standard mode".
2. Remove the test device from the foil pouch, and insert it into the BIONOTE Vcheck Analyzer.
3. "Apply sample" will appear on the display of the BIONOTE Vcheck Analyzer.

[Dilution of sample & Measurement]

1. Using a disposable capillary tube, draw 25µl of sample into the tip and add the sample to a assay diluent tube(175µl).
2. Using a disposable tablet sputit(orange bulb), mix well by gently squeezing the rubber bulb(orange) several times until the lavender tablet dissolves in the sputit.
3. Add all of the mixed sample/tablet into the sample hole of the test device using a disposable tablet sputit(orange bulb) and press the START to initiate testing.

[Interpretation of the Result]

1. Read the concentration value of canine pancreas-specific lipase appearing on the display of the BIONOTE Vcheck Analyzer.(50~2000ng/mL)
2. If "<50ng/mL" appears on the display, it means the concentration of canine pancreas-specific lipase in the specimen is less than to 50ng/mL.
3. If ">2000ng/mL" appears on the display, it means the concentration of canine pancreas-specific lipase in the specimen is greater than to 2000ng/mL.

[Screen messages and Trouble shooting]

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 blood has been applied. Solution: Retest with the new test device with an enough specimen, ensuring that blood is placed to the narrow channel in the top edge of the test device.
Expired Device	The test devices are expired. Solution: Retest with the new test device with non-expired date.
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 is failed. Solution: Connect again between analyzer and external device. If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.
Barcode Error	
Extremely Total hemoglobin	The measured total hemoglobin is out of the range of 7 to 23g/dL. Solution: This error occurs with a specimen known to have 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 the new test device and the new patient's 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 test device is not proper for the analyzer. Solution: Check the type of the test device whether it is manufactured by BioNote, Inc.
EEE	Internal error has appeared. Solution: If the error continues after turning ON/OFF the analyzer, please contact BioNote, Inc.

[Performance characteristic]

1. Analytical specificity
No other canine blood components are known to cross react with canine pancreas-specific lipase in the Vcheck cPL Test kit.
2. Interference
Measurement was not influenced by interfering substances such as triglyceride, bilirubin.
3. Measuring Range
50~2000ng/mL of canine pancreas-specific lipase is measurable in serum. For >2000ng/mL results, samples may be diluted with PBS buffer and re-measured for a numerical result. To calculate the final canine pancreas-specific lipase concentration, the measured result must be multiplied by the dilution factor.

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