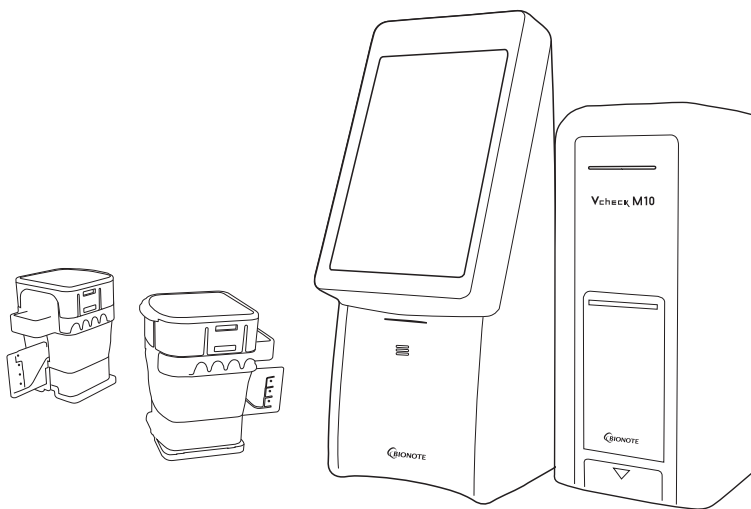


FOR VETERINARY USE ONLY

Vcheck M FIV/FeLV

For use with Vcheck M10 system



 **BIONOTE**

TABLE OF CONTENTS

1. Intended Use
2. Summary and Explanation
3. Principle of the Procedure
4. Materials Provided
5. Storage and Handling
6. Materials Required but Not Provided
7. Warnings and Precautions
8. Sample Collection, Transport, and Storage
9. Procedure
10. Interpretation of Results
11. Performance
12. Limitations
13. References
14. Symbols

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1. Intended Use

The Vcheck M FIV/FelV test is a multiplex real-time RT-PCR test intended for use with Vcheck M10 system for the qualitative detection of nucleic acids from Feline immunodeficiency virus (FIV) and Feline leukemia virus (FeLV) in whole blood (EDTA) collected from cats.

Results are for the identification of FIV and FeLV RNA. Positive results are indicative of the presence of FIV and FeLV RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out co-infection with other viruses or bacteria. The agent detected may not be the definite cause of disease.

Negative results do not preclude FIV and FeLV infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Vcheck M FIV/FelV test is intended to be performed by trained users in both laboratory and animal hospitals.

2. Summary and Explanation

FIV and FeLV are both retroviruses in the Retroviridae family. FeLV can lead to progressive, regressive, or abortive infections, causing various related diseases. FIV, a Lentivirus like HIV, weakens the immune system by targeting Helper T cells. FIV infection progresses through primary, asymptomatic, and secondary phases, potentially leading to immunodeficiency, secondary infections, and tumors in cats. Both viruses are primarily transmitted through bite wounds or close contact.

This kit is supportive for the diagnosis of infection of FIV and FeLV. The test results are only for clinical reference and cannot be used as a basis for confirming or excluding cases by itself.

The Vcheck M FIV/FelV test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of FIV and FeLV and is based on widely used nucleic acid amplification technology. The Vcheck M FIV/FelV test contains primers and probes and internal control (IC) used in PCR for the *in vitro* qualitative detection of FIV and FeLV in whole blood (EDTA) samples.

Cartridge Description

The Vcheck M FIV/FelV cartridge is a disposable plastic device that allows performance of fully automated molecular assays by containing all reagents required for the test.

Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the part to their intended destinations.

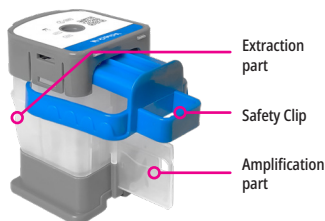


Figure 1. Layout of the Vcheck M FIV/FelV cartridge

3. Principle of the Procedure

The Vcheck M FIV/FeLV test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from FIV and FeLV. The Vcheck M FIV/FeLV test is performed on Vcheck M10 system.

The Vcheck M10 system automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in various samples using molecular diagnostic assays. The system consists of the Vcheck M10 Module and the Vcheck M10 Console with preloaded software for running tests and viewing the results. The system requires the use of single-use cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross contamination between samples is minimized. For a full description of the systems, see the Vcheck M10 system User Manual.

The Vcheck M FIV/FeLV test includes reagents for the detection of DNA from FIV and FeLV in whole blood (EDTA) samples. The cartridge is present to control for adequate processing of the sample and PCR reaction. The table below indicates which target is designed to be detected by which channel.

Table 1. Fluorescent channel of each target gene pathogen

Target	channel
FeLV	HEX
FIV	FAM
Internal control (IC)	Cy5

4. Materials Provided

The Vcheck M FIV/FeLV kit contains sufficient reagents to process 5 samples or quality control samples.

Table 2. Contents of the Vcheck M FIV/FeLV kit

Contents	Quantity	Usage in each reaction	Note
Cartridge	5	1 ea	
EDTA tube	5	1 ea	Purple cap
Buffer tube	5	1 ea	Yellow cap
Pipette tip (White)	5	1 ea	1~200 µl
Pipette tip (Blue)	5	1 ea	100~1000 µl
Quick Reference Instructions	1	-	
Instructions for Use	1	-	

5. Storage and Handling

Store the Vcheck M FIV/FeLV kit at 2–28 °C (36–82 °F). If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at room temperature. Do not remove the Safety Clip of the cartridge and do not press the cartridge until actual use. Do not use a cartridge that has leaked or is wet. Under these conditions, cartridges can be stored until the expiration date printed on the packaging.

6. Materials Required but Not Provided

- Vcheck M10 system with User Manual
At least one Vcheck M10 Console and one Vcheck M10 Module
- Sample collection tools
Sterile syringe
- Sample transfer pipettes
- PPE (Personal Protective Equipment)
- Biohazard container
- Quality control samples (Positive control, Negative control)

7. Warnings and Precautions

1. This kit is only for *in vitro* diagnostic for cats.
2. If the test is not performed according to the Instructions for Use, inaccurate results may be obtained.
3. Do not use this kit with any product other than the Vcheck M10 suggested by the manufacturer.
4. Samples can contain an unknown virus or bacteria, so be careful when handling them. If contamination is suspected, replace all tools and discard used reagents immediately.
5. It is recommended that the solid waste used in the experiment be sterilized by autoclaving at 121 °C for at least 15 minutes, and must be safely disposed of by national or regional regulations.
6. This kit must be used by mixing 100 µl of feline whole blood (EDTA) with the supplied buffer.
7. If whole blood (EDTA) is used in an amount less than 100 µl, false negative results may occur, and if used directly without mixing with buffer, and driving error may occur.
8. Use the supplied tube and tip or use a sterile disposable tube and tip.
9. Minimize exposure of the cartridge to light.
10. Do not remove the Safety Clip of the cartridge before use.
11. Do not press the cartridge until actual use. If the cartridge is exposed to moisture, the performance may deteriorate.

12. Do not use a cartridge that has leaked or is wet.
13. Do not shake the cartridge as much as possible and be careful not to spill the reagent by turning over an opened cartridge.
14. Direct contact, such as touching the amplification part of the cartridge, may affect the test result, so do not touch it with your hands.
15. Test within 10 minutes after dispensing the sample into the cartridge.
16. Cartridges are for single use only, so do not reuse processed cartridges.
17. Do not use a cartridge with a damaged barcode label.
18. Do not use reagents whose expiration date has passed.
19. A professional veterinarian must make a final diagnosis based on the results of this kit and other test results and clinical findings.

8. Sample Collection, Transport, and Storage

Proper sample collection, transportation, and storage are critical to the performance of the test. Improper sample collection, inappropriate sample handling and/or transportation can lead to false results.



Figure 2. Blood sample collection

1. Collect the whole blood with a sterile syringe.
2. Put the collected whole blood into an EDTA tube (purple cap) and invert the tube 5–6 times.
3. The samples should be used immediately after collection. If samples are not tested immediately, it can be used for 3 days when refrigerated. For longer storage, freezing is recommended.
4. Close the lid to prevent drying.

9. Procedure

Starting the Vcheck M10 system



For the detailed instructions, refer to the Vcheck M10 system User Manual.

If you have scanned the cartridge barcode in the Vcheck M10 and the software version is not compatible, a 'Not Supported Device' error message appears. Update the software before proceeding the test.

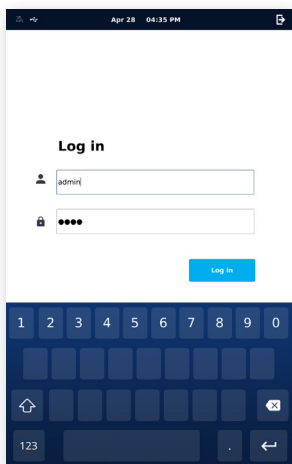


Figure 3. Log In screen

1. Turn on the Vcheck M10 system.
2. Check the Vcheck M10 Console and the Vcheck M10 Module is connected and functional.
3. Enter the ID and Password on the Log In screen of the Vcheck M10 Console and click the **Log in** button.

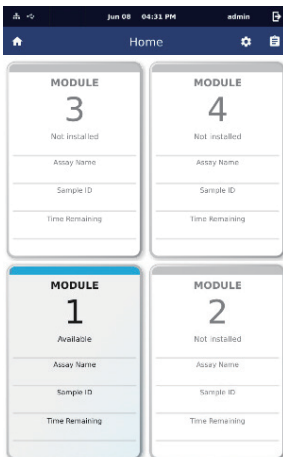


Figure 4. Home screen

4. Touch the Vcheck M10 Module to run on the Home screen.

(The door of the selected Vcheck M10 Module will automatically open for cartridge loading.)

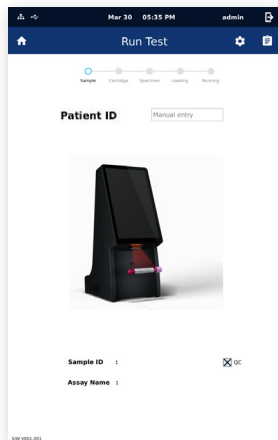


Figure 5. Entering Patient ID

5. Enter a Patient ID by scanning the barcode or using virtual keyboard on the M10 Console screen.

(Patient ID is optional. You can turn off the Patient ID option from the 'Settings'.)

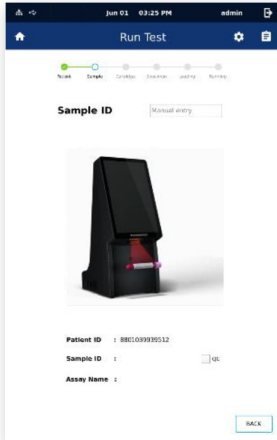


Figure 6. Entering Sample ID

6. Enter a Sample ID by scanning the barcode of the sample or using virtual keyboard on the M10 Console screen.
(For quality control test, tick the QC check box.)

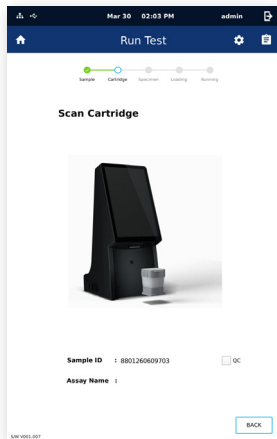


Figure 7. Scanning a cartridge

7. Scan the Vcheck M FIV/FeLV cartridge to be used. The Vcheck M10 Module automatically recognizes the assay to be run based on the cartridge barcode.

Loading a sample into the Vcheck M FIV/FeLV cartridge



If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at room temperature.

Start the test within 10 minutes of loading the sample into the Vcheck M FIV/FeLV cartridge.



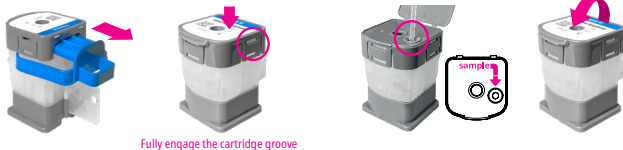
Note

False negative results may occur if insufficient sample is added into the cartridge.



Figure 8. Sample Guide screen

1. Remove the Safety Clip located underneath the lid of the cartridge.
2. Pierce the sealed cartridge by pressing down the lid until fully engaged into the cartridge groove.
 - *Caution: Incomplete engaging may cause a driving error.
3. Using a 100 μ l or 200 μ l pipette with white pipette tip, add 100 μ l of blood (EDTA) into a Buffer tube (yellow cap), and mix by pipetting for 5–6 times.
4. Open the cartridge lid and check that the seal is completely punctured before loading a sample.
5. Using a pipette with blue pipette tip, dispense 600 μ l of the sample into the sample hole.
 - *If you collect after brief centrifugation, 600 μ l of sample can be collected more smoothly.
 - *Test within 10 minutes after dispensing the sample into the cartridge.
6. After a few seconds, Sample Guide screen will automatically change to the Insert Cartridge screen. Touch the Sample Guide screen if you want to skip the guide.
7. Close the cartridge lid.



Fully engage the cartridge groove

Figure 9. Loading a sample

Running a test



Figure 10. Insert Cartridge screen

1. Load the cartridge on the selected Vcheck M10 Module with the Amplification part facing the inside of the module.

(The status indicator of the selected module will blink green.)

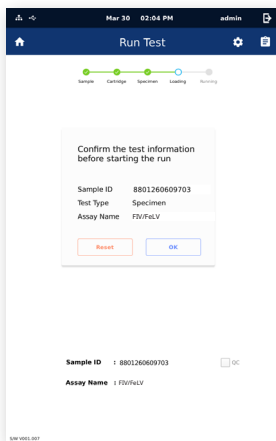


Figure 11. Confirm the test screen

2. Close the door completely.
3. After confirm the sample and cartridge information, touch the **OK** button on the screen.

(Touch the **Reset** button to re-input the information.)

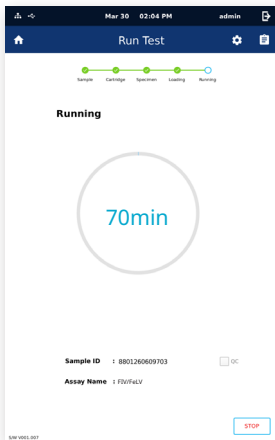


Figure 12. Running screen

4. Assay starts automatically, and remaining time will appear on the screen.

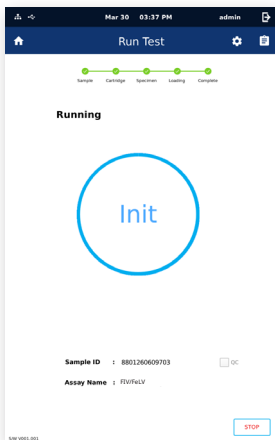



Figure 13. Test complete

5. When the run is finished, it switches to the Review screen and the result is displayed.
6. Dispose of used cartridges in the appropriate sample waste containers according to your institution's standard practices.
7. To run another test, touch the Home icon  and repeat the process.

(If another Vcheck M10 Module connected to the Vcheck M10 Console is available, you can start a new test while another test is running.)

10. Interpretation of Results

The results are interpreted automatically by the Vcheck M10 Console and are clearly shown in the Review screen. The interpretation of the Vcheck M FIV/FelV test results is determined based on Table 3. If an invalid result is obtained, perform a retest.

Table 3. Interpretation of results

Result	FIV	FelV	Internal Control
+ FIV/FelV Positive	+	+	V
+ FIV Positive	+	-	V
+ FelV Positive	-	+	V
- FIV/FelV Negative	-	-	V
! Invalid / Re-test	-	-	!

11. Performance

1. Analytical Sensitivity

[LOD, Limit of Detection]

Target	LOD (copies/mL)
Feline immunodeficiency virus	1.4×10^3
Feline leukemia virus	1.4×10^3

2. Analytical Specificity

- Interference

There was no interference for potential interfering substance listed below.

[Table of Substance and Concentration]

Substance	Concentration
Hemoglobin	50 g/dL
Bilirubin	5 mg/dL
Triglyceride	50 mg/dL
Cholesterol	150 mg/dL
Vitamin C	100 mg/dL

- Cross reactivity

There was no cross-reaction with pathogens associated with feline diseases in the whole blood samples for the following high-concentration substances, as listed below.

No	Substance	Result
1	Feline coronavirus	No cross-reaction
2	<i>Tritrichomonas foetus</i>	No cross-reaction
3	<i>Giardia intestinalis</i>	No cross-reaction
4	<i>Campylobacter jejuni</i>	No cross-reaction
5	<i>Toxoplasma gondii</i>	No cross-reaction
6	Feline Parvovirus	No cross-reaction
7	<i>Salmonella Enteritidis</i>	No cross-reaction
8	<i>Leptospira pomona</i>	No cross-reaction
9	<i>Leptospira icterohaemorrhagiae</i>	No cross-reaction
10	<i>Leptospira australis</i>	No cross-reaction
11	<i>Leptospira grippityphosa</i>	No cross-reaction
12	<i>Leishmania infantum</i>	No cross-reaction
13	<i>Leishmania donovani</i>	No cross-reaction
14	<i>Leptospira bratislava</i>	No cross-reaction
15	<i>Leishmania mexicana</i>	No cross-reaction
16	<i>Ehrlichia chaffeensis</i>	No cross-reaction
17	<i>Anaplasma phagocytophilum</i>	No cross-reaction
18	<i>Borrelia garinii</i>	No cross-reaction
19	<i>Borrelia afzelii</i>	No cross-reaction
20	<i>Borrelia burgdorferi</i>	No cross-reaction
21	<i>Bartonella henselae</i>	No cross-reaction
22	<i>Bartonella koehlerae</i>	No cross-reaction

3. Precision

In the repeatability and reproducibility tests using the standard materials, it was confirmed that all of the samples met the test standards for finished products.















11. Limitations

1. This kit must use whole blood (EDTA) from cats.
2. This kit can detect the RNA of FIV (subtype A, B, C, D, E, F, and U-NZenv), but cannot distinguish them.
3. This kit can detect RNA of FeLV (subtype A, B, C, and T), but cannot distinguish them.
4. Failure to follow the procedures in this IFU may result in inaccurate results.
5. Contamination of the laboratory environment, contamination of cartridges, and cross-contamination of samples can lead to false-positive results.
6. Incorrect handling of the kit during movement, storage and use may reduce the sensitivity of the reagent detection results and lead to erroneous results.
7. This kit is designed to automatically perform nucleic acid extraction, amplification and detection of FIV and FeLV, but if a mutation occurs in the detection target sequence, it may not be detected.

12. References

1. ME Westman et al., Diagnosing feline immunodeficiency virus (FIV) and feline leukaemia virus (FeLV) infection: an update for clinicians, Volume97, Issue 3, Australian Veterinary Journal, Pages 47-55, March 2019.
2. Alvaro Arjona et al., Evaluation of a novel nested PCR for the routine diagnosis of feline leukemia virus (FeLV) and feline immunodeficiency virus (FIV), Journal of Feline Medicine and Surgery, Volume 9, Issue 1, Pages: 14 - 22, February 2007

13. Symbols

Symbols	Description	Symbols	Description
	Manufacturer		Note
	Consult instructions for use		Use by date
	Reference number		Temperature limit
	Batch code		Do not re use
	Date of manufacture Indicates the date of manufacture		Indicates to keep the analyzer dry that you should keep the analyzer dry
	Do not use if packaging is damaged		Keep away from sunlight
	Contains Sufficient for <n> Tests		<i>In vitro</i> diagnostics medical device

Vcheck M FIV/FeLV

For use with Vcheck M10 system



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