

FOR VETERINARY USE ONLY

Vcheck M

Babesia gibsoni/canis

For use with Vcheck M10 system



 **BIONOTE**

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 VCM102AC

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1. Intended Use

The Vcheck M *Babesia gibsoni*/*canis* test is a multiplex real-time PCR test intended for use with Vcheck M10 system for the qualitative detection of nucleic acids from *Babesia gibsoni* and *Babesia canis* in whole blood (EDTA) collected from dogs.

Results are for the identification of *Babesia gibsoni* and *Babesia canis* DNA. Positive results are indicative of the presence of *Babesia gibsoni* and *Babesia canis* DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out viral infection or co-infection with other bacteria or protozoa. The agent detected may not be the definite cause of disease.

Negative results do not preclude *Babesia gibsoni* and *Babesia canis* 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 *Babesia gibsoni*/*canis* test is intended to be performed by trained users in both laboratory and animal hospitals.

2. Summary and Explanation

B. gibsoni and *B. canis* are protozoan parasites that are transmitted by ticks to dogs, and are the causative agents of Canine Babesiosis, respectively. They are important tick-borne diseases with a worldwide distribution. They can cause a variety of ranging in severity from a sudden collapse with systemic shock, to a hemolytic crisis, to a subtle and slowly progressing infection with no apparent clinical signs.

This kit is supportive for the diagnosis of infection of *B. gibsoni* and *B. canis* (*B. canis canis*, *B. canis vogeli*, *B. canis rossii*). 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 *Babesia gibsoni*/*canis* test is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of *Babesia gibsoni* and *Babesia canis* and is based on widely used nucleic acid amplification technology. The Vcheck M *Babesia gibsoni*/*canis* test contains primers and probes and internal control (IC) used in PCR for the *in vitro* qualitative detection of *Babesia gibsoni* and *Babesia canis* DNA in whole blood (EDTA) samples.

Cartridge Description

The Vcheck M *Babesia gibsoni*/*canis* 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.

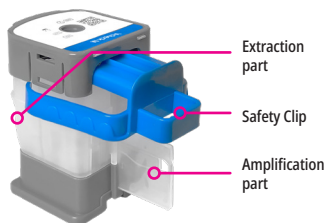


Figure 1. Layout of the Vcheck M *Babesia gibsoni*/*canis* cartridge

3. Principle of the Procedure

The Vcheck M *Babesia gibsoni*/*canis* test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from *Babesia gibsoni* and *Babesia canis*. The Vcheck M *Babesia gibsoni*/*canis* 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 *Babesia gibsoni*/*canis* test includes reagents for the detection of DNA from *Babesia gibsoni* and *Babesia canis* 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
<i>Babesia gibsoni</i>	FAM
<i>Babesia canis</i> (<i>B. canis canis</i> , <i>B. canis vogeli</i> , <i>B. canis rossii</i>)	HEX
Internal control (IC)	Cy5

4. Materials Provided

The Vcheck M *Babesia gibsoni*/*canis* kit contains sufficient reagents to process 5 samples or quality control samples.

Table 2. Contents of the Vcheck M *Babesia gibsoni*/*canis* 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 Babesia gibsoni/canis 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* diagnostics for dogs.
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, bacteria, or protozoa, 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 canine 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.

Starting the Vcheck M10 system



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 2 days when refrigerated.
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.

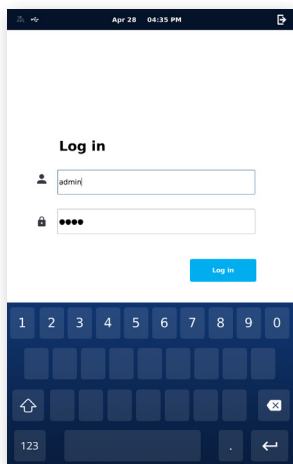


Figure 3. Log In screen

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.

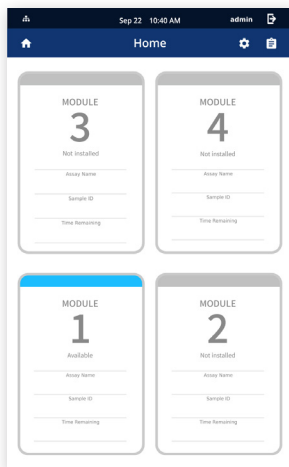


Figure 4. Home screen

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'.)

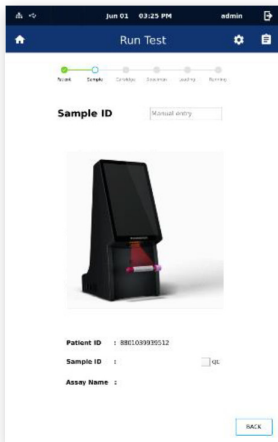


Figure 6. Entering Sample ID

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.)

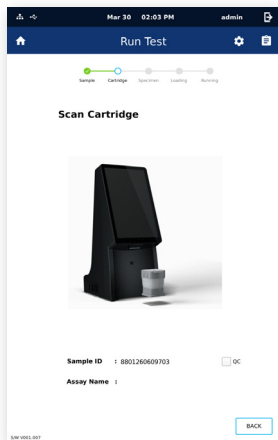


Figure 7. Scanning a cartridge

7. Scan the Vcheck M Babesia gibsoni/canis 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 Babesia gibsoni/canis 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 Babesia gibsoni/canis 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.

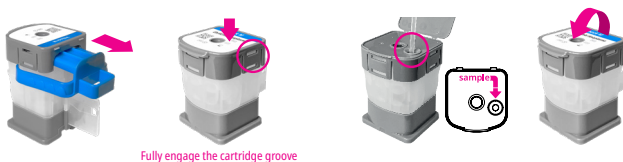
*Caution: Incomplete engaging may cause a driving error.

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.)

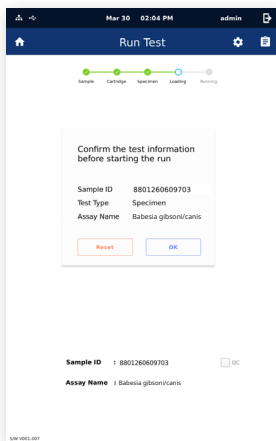


Figure 11. Confirm the test screen

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.)

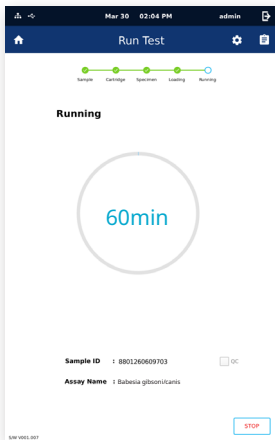
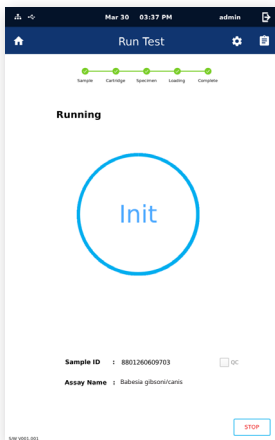



Figure 12. Running screen

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



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 Babesia gibsoni/canis test results is determined based on Table 3. If an invalid result is obtained, perform a retest.

Table 3. Interpretation of results

Result	<i>Babesia gibsoni</i>	<i>Babesia canis</i>	Internal Control
+ Babesia gibsoni/canis Positive	+	+	✓
+ Babesia gibsoni Positive	+	-	✓
+ Babesia canis Positive	-	+	✓
- Babesia gibsoni/canis Negative	-	-	✓
! Invalid / Re-test	-	-	!

11. Performance

1. Analytical Sensitivity

[LOD, Limit of Detection]

Target	Subtype	LOD (copies/mL)
<i>Babesia gibsoni</i>	<i>Babesia gibsoni</i>	17,782.8
	<i>Babesia canis canis</i>	9,549.9
<i>Babesia canis</i>	<i>Babesia canis vogeli</i>	8,912.5
	<i>Babesia canis rossi</i>	7,244.4

2. Analytical Specificity

· Interference

There was no interference for potential interfering substance listed below.

Substance	Concentration
Hemoglobin	10 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 potential cross-reactive substances, such as tick-borne pathogens and canine disease pathogens listed below.

No	Substance	Result
1	<i>Ehrlichia canis</i>	Negative
2	<i>Anaplasma phagocytophilum</i>	Negative
3	<i>Borrelia burgdorferi</i>	Negative
4	<i>Bartonella henselae</i>	Negative
5	<i>Leptospira interrogans</i>	Negative
6	<i>Leishmania infantum</i>	Negative
7	Canine Distempervirus	Negative
8	Canine Adenovirus 1	Negative

3. Precision

In the repeatability and reproducibility tests using the standard materials, it was confirmed that all of the negative and 3 positive samples met the test standards for finished products.

12. Limitations















1. This kit must use whole blood (EDTA) from dogs.
2. This kit can detect DNA of *Babesia canis canis*, *Babesia canis vogeli*, and *Babesia canis rossi*, but cannot distinguish them.
3. Failure to follow the procedures in this IFU may result in inaccurate results.

- Contamination of the laboratory environment, contamination of cartridges, and cross-contamination of samples can lead to false-positive results.
- Incorrect handling of the kit during movement, storage and use may reduce the sensitivity of the reagent detection results and lead to erroneous results.
- This kit is designed to automatically perform DNA extraction, amplification and detection of *Babesia gibsoni* and *Babesia canis*, but if a mutation occurs in the detection target sequence, it may not be detected.

13. References

- I-Li Liu, et al. 2019. A novel PCR-based point-of-care method enables rapid, sensitive and reliable diagnosis of *Babesia gibsoni* infection in dogs. BMC Veterinary Research volume 15, Article number: 428 (2019)
- Adam J. Birkenheuer. Development and Evaluation of a Seminested PCR for Detection and Differentiation of *Babesia gibsoni* (Asian Genotype) and *B. canis* DNA in Canine Blood Samples. J Clin Microbiol. 2003 Sep; 41(9): 4172–4177.

14. 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
	<i>In vitro</i> diagnostics medical device		Keep away from sunlight
	Contains Sufficient for <n> Tests		Do not use if packaging is damaged

Vcheck M

Babesia gibsoni/canis

For use with Vcheck M10 system



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