

Vcheck M

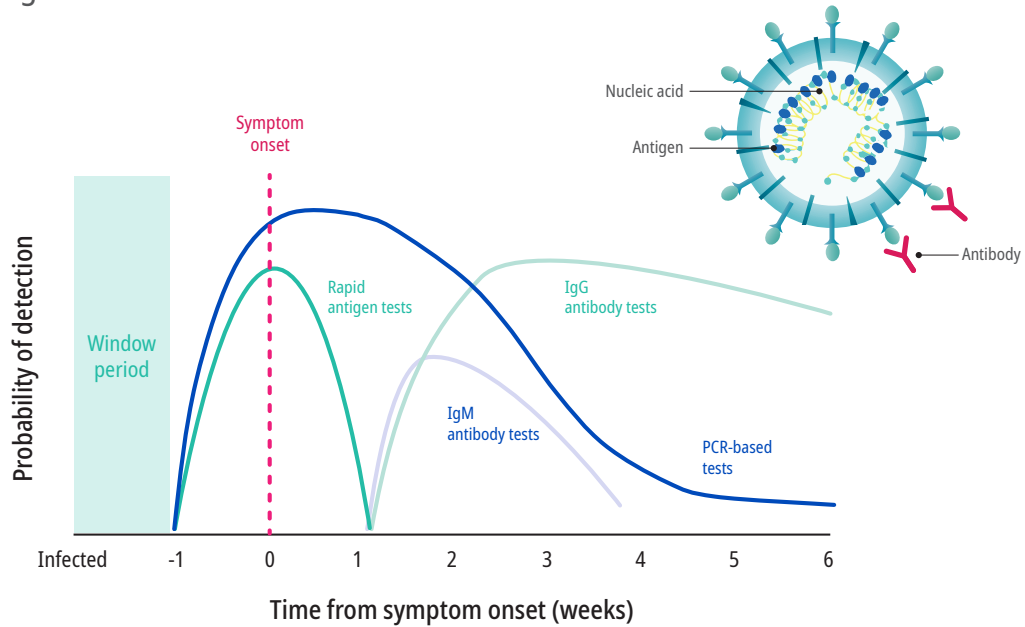
State-of-the-art POC Molecular Diagnostic System



BIONOTE

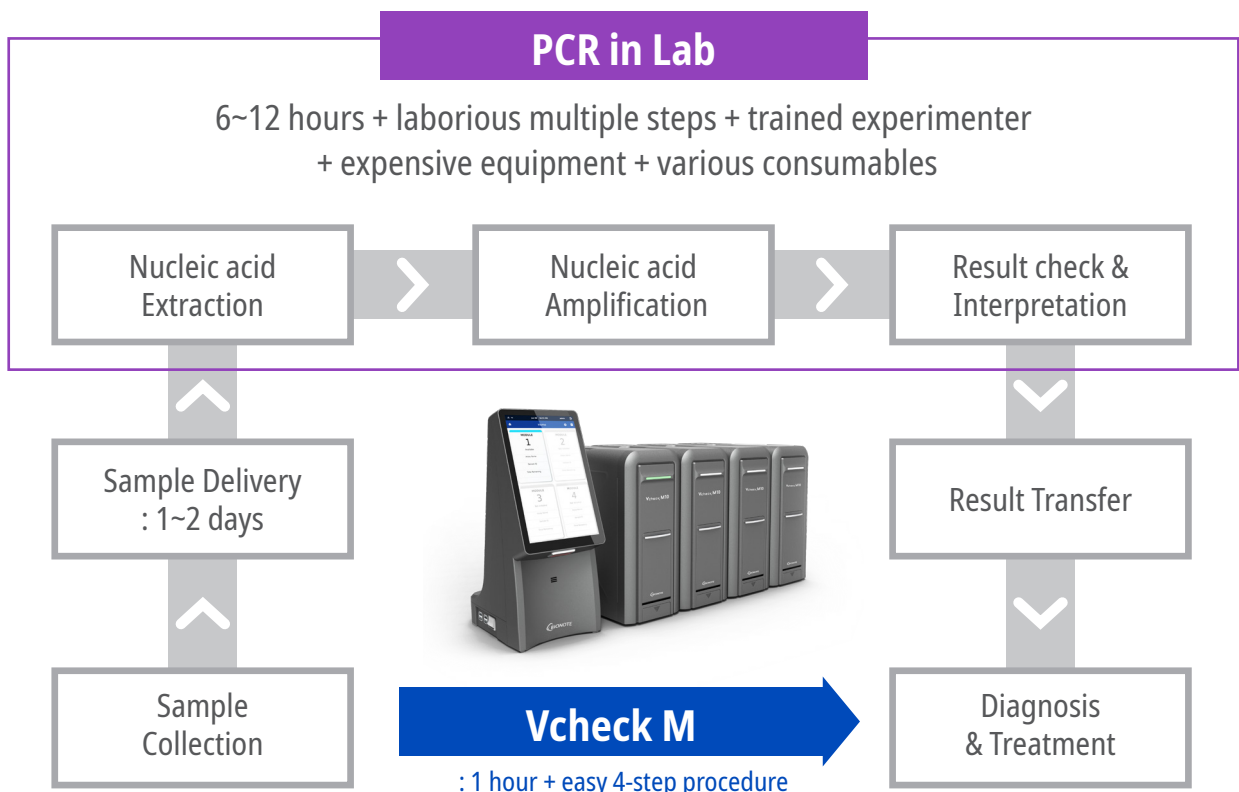
Why PCR?

- High sensitivity & specificity ▶ Accurate result
- Earlier diagnosis ▶ Effective treatment



* Reference: Giorgia Guglielmi, Fast coronavirus tests: what they can and can't do, Nature 585, 496-498 (2020)

Limitations of existing PCR



Vcheck M10 Analyzer

Fast Results

Sample in → Result out
in about 1 hour

Multiplex

Maximum 12 targets
in a cartridge

Various Setting

Applicable for various species,
sample types, pathogens



Simple Procedure

Automated extraction,
amplification,
and data analysis

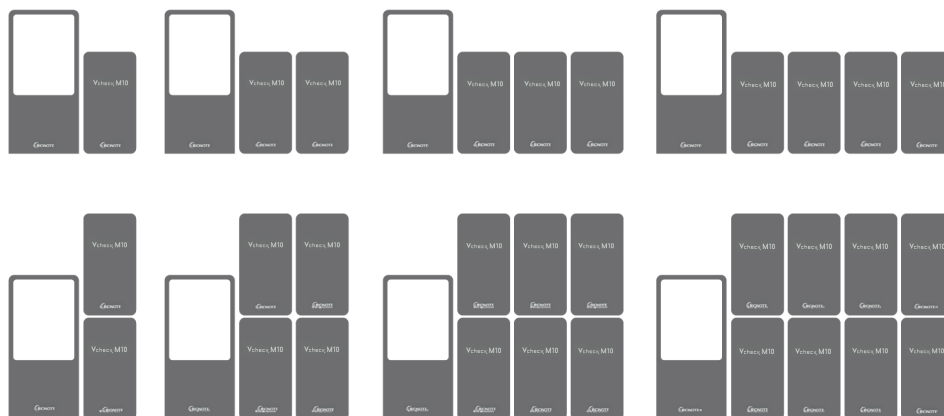
Good Accuracy

High sensitivity
and specificity

Modular & Scalable

Scalable configuration with
up to 8 modules

**Vcheck M10 can be used anywhere diagnostics are needed,
from vet clinics to specialized laboratory**



Vet clinic



Laboratory

Vcheck M10



M10 Console

Simple & Easy Controller
Accurate Data Manager

- 10.1" touch screen
- Internal barcode scanner
- User friendly interface with animated guide
- Stored up to 5,000 results
- Seamless connectivity (LIS/HIS)
- Accurate data analysis algorithm

M10 Module

Randomly
Accessible Analyzer

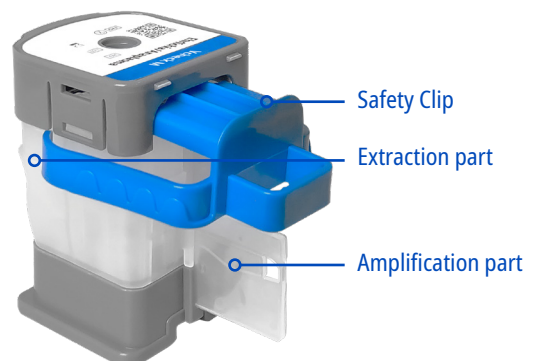
- Minimum maintenance requirements
- Intuitive status indicator
- Compact size
- Easy connection between Modules
- Customized configuration up to 8 modules



Vcheck M Cartridge

All-in-one Cartridge
Multiplex assay up to 12-Plex

- Simple 'Sample-in Result-out' workflow
- Result in an hour
- Reliable result by accumulated technologies
- Multiplex assay up to 12-plex including IC
- Room temperature storage
- Prevention of contamination & easy disposal



Easy 4-step test procedure

1 Scan the sample ID



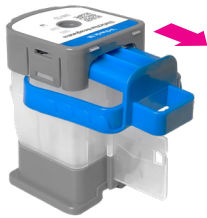
2 Scan the cartridge code



3 Apply the sample & close the cartridge



4 Insert the cartridge



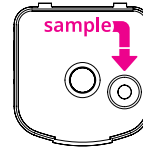
Remove the safety clip



Press down the lid



Dispense the sample

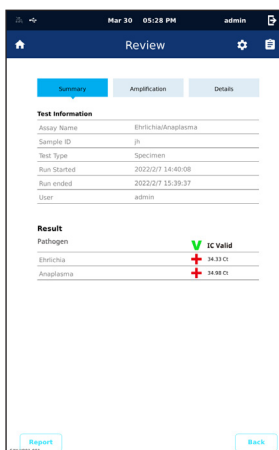


Close the lid

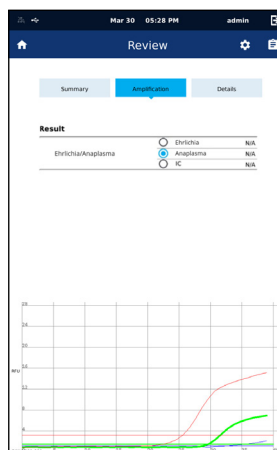
Automatic Result Reading

- No need to set threshold or read result according to cut-off
- Ct value and amplification curve can be checked

Summary



Amplification



Details



Canine Vector-borne/Anemia disease

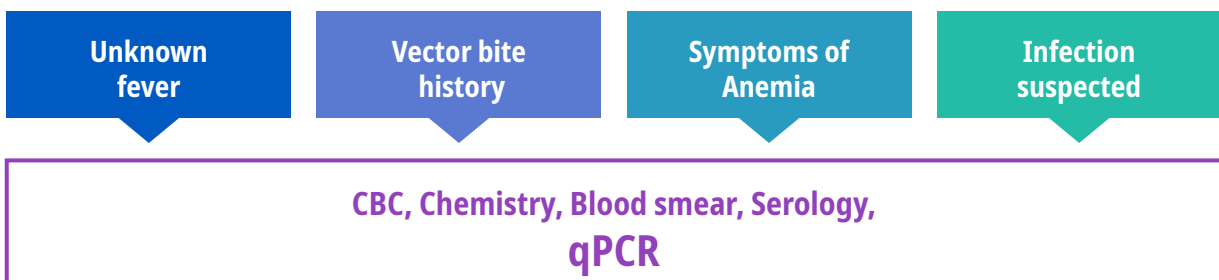
Disease Summary

Vector	Disease	Pathogen	Clinical signs
Tick	Ehrlichiosis	<i>Ehrlichia</i> spp. <i>E. canis</i> , <i>E. ewingii</i> , <i>E. chaffeensis</i>	lymphadenopathy, cough, bleeding disorder
	Anaplasmosis	<i>Anaplasma</i> spp. <i>A. phagocytophilum</i> , <i>A. platys</i>	lameness, joint pain
	Babesiosis	<i>Babesia</i> spp. <i>B. gibsoni</i> , <i>B. canis canis</i> , <i>B. canis vogeli</i> , <i>B. canis rossii</i>	Hemolysis, red urine, splenomegaly, jaundice
	Rocky mountain spotted fever	<i>Rickettsia</i> sp. <i>R. rickettsii</i>	muscle/joint pain, cough, vomiting, diarrhea, edema
	Hepatozoonosis	<i>Hepatozoon</i> spp. <i>H. americanum</i> , <i>H. canis</i>	lymphadenopathy, muscle pain, eyes/nose discharge
	Lyme Borreliosis	<i>Borrelia</i> spp. <i>B. burgdorferi</i> , <i>B. afzelii</i> , <i>B. garinii</i>	lameness, renal disease, cardiac disease, hepatic disease
Flea	Hemoplasmosis	<i>Mycoplasma</i> spp. <i>M. hemocanis</i>	hemolysis, pallor
	Bartonellosis	<i>Bartonella</i> spp. <i>B. henselae</i> , <i>B. koehlerae</i>	lymphadenopathy, muscle pain, vomiting, diarrhea, cough
Sand fly	Leishmaniosis	<i>Leishmania</i> spp. <i>L. infantum</i> , <i>L. donovani</i> , <i>L. mexicana</i>	lymphadenopathy, diarrhea, vomiting, alopecia, skin lesions
-	Leptospirosis	<i>Leptospira</i> spp. <i>L. autumnalis</i> , <i>L. grippityphosa</i> , <i>L. bratislava</i> , <i>L. pomona</i> , <i>L. canicola</i> , <i>L. icterohaemorrhagiae</i>	bleeding, jaundice, vomiting, diarrhea, abdominal discomfort

Fever,
Lethargy/
depression,
Anorexia/
weight loss,
Anemia

Diagnosis

- Help confirm the pathogen causing clinical signs
- Selection of appropriate treatment regimen
- Early prevention of spread of pathogens
- Minimize human exposure to pathogens

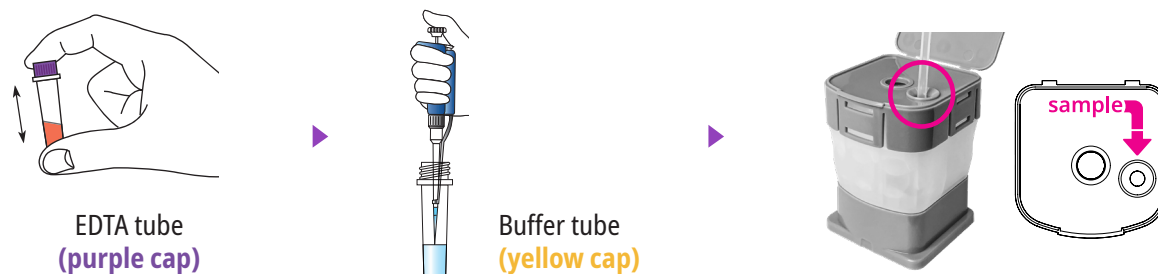


Vcheck M cartridge for Vector/Anemia panel

Specification

Product Name	Ehrlichia/ Anaplasma	Babesia gibsoni/canis	Canine Vector 8 Panel	Canine Anemia 8 Panel
Detection target	<i>Ehrlichia</i> spp., <i>Anaplasma</i> spp.	<i>Babesia gibsoni</i> , <i>Babesia canis</i>	<i>Ehrlichia</i> spp., <i>Hepatozoon</i> spp., Hemoplasma, <i>Anaplasma</i> spp., <i>Rickettsia rickettsii</i> , <i>Babesia</i> spp.	
			<i>Leishmania</i> spp., <i>Bartonella</i> spp.	<i>Borrelia</i> spp., <i>Leptospira</i> spp.
Species	Canine, Feline	Canine	Canine	Canine
Sample	Whole blood (EDTA) 100 µl			
Testing Time	70 min.	60 min.	70 min.	70 min.
Results	Qualitative & Semi-quantitative (Ct value, Amplification curve)			
Storage Temp.	2~28 °C			
Shelf life	12 months			
Packing Unit	5 Tests/Kit			

- Sample dilution : Blood 100 µl + Buffer 500 µl ▶ Dispense 600 µl



Clinical Performance

Product	Test Category	Sen.	Spe.	Comparison test	Confirmation test
Ehrlichia/Anaplasma	<i>Ehrlichia</i> spp.	100%	100%	Real-time PCR ¹	Sequencing
	<i>Anaplasma</i> spp.	100%	100%	Real-time PCR ¹	Sequencing
Babesia gibsoni/canis	<i>Babesia gibsoni</i>	100%	100%	Real-time PCR ²	Sequencing
	<i>Babesia canis</i>	100%	100%	Nested PCR ³	Sequencing

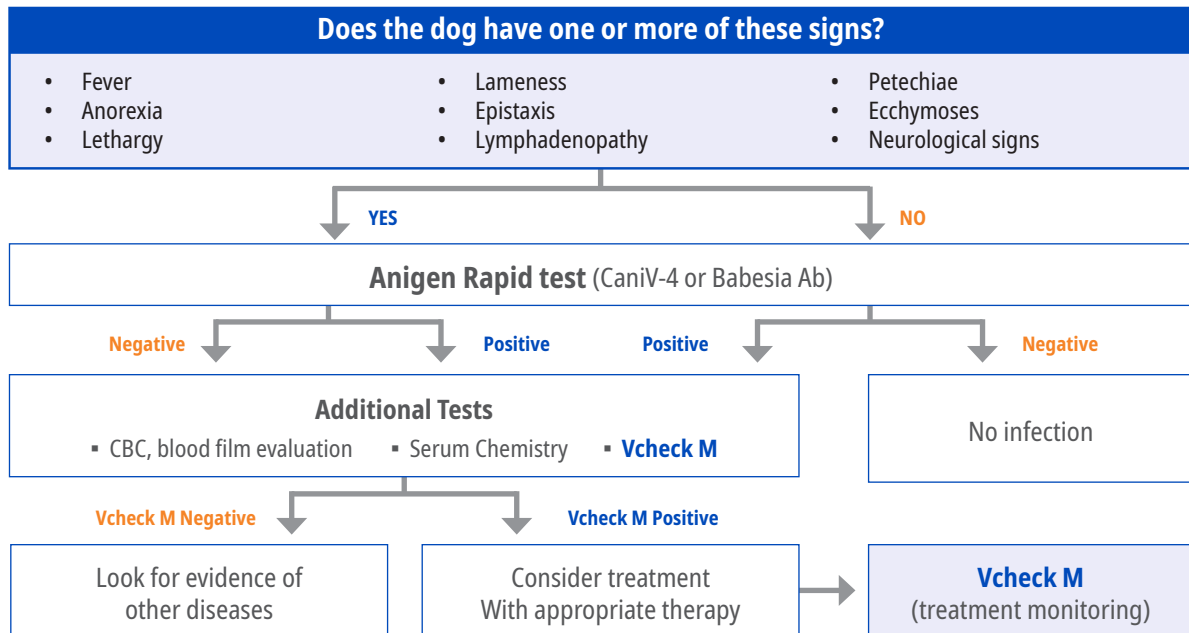
1. SD Biosensor, Inc. R&D department

2. Commercial laboratory in Korea

3. College of veterinary medicine in Poland

Vcheck M cartridge for Vector/Anemia panel

Diagnostic Algorithm



Ordering Information

Analyzer

Product	Contents	Cat No.
Vcheck M10 Console	1 M10 Console (Operational module)	VCM752EA
Vcheck M10 Module	1 M10 Module (Analytical module)	VCM753EA

Cartridge

Product	Pathogen	Cat No.
Vcheck M Ehrlichia/Anaplasma	<i>Ehrlichia</i> spp., <i>Anaplasma</i> spp.	VCM101AC
Vcheck M Babesia gibsoni/canis	<i>Babesia gibsoni</i> , <i>Babesia canis</i>	VCM102AC
Vcheck M Canine Vector 8 Panel	<i>Ehrlichia</i> spp., <i>Hepatozoon</i> spp., Hemoplasma, <i>Anaplasma</i> spp., <i>Rickettsia rickettsii</i> , <i>Babesia</i> spp., <i>Leishmania</i> spp., <i>Bartonella</i> spp.	VCM104AC
Vcheck M Canine Anemia 8 Panel	<i>Ehrlichia</i> spp., <i>Hepatozoon</i> spp., Hemoplasma, <i>Anaplasma</i> spp., <i>Rickettsia rickettsii</i> , <i>Babesia</i> spp., <i>Borrelia</i> spp., <i>Leptospira</i> spp.	VCM105AC
Vcheck M ASFV*	ASFV	VCM106AC
Vcheck M FIV/FeLV*	FIV, FeLV	-
Vcheck M Canine Diarrhea 8 Panel*	Canine parvovirus type 2 (CPV-2), Enteric coronavirus (CECoV), Canine distemper virus (CDV), <i>Giardia</i> spp., <i>Cryptosporidium</i> spp., <i>Salmonella</i> spp., <i>Clostridium perfringens</i> , <i>Campylobacter</i> spp.	-
Vcheck M Feline Diarrhea 8 Panel*	Feline panleukopenia virus (FPV), Feline coronavirus (FCoV), <i>Giardia</i> spp., <i>Tritrichomonas foetus</i> , <i>Toxoplasma gondii</i> , <i>Salmonella</i> spp., <i>Campylobacter</i> spp., <i>Cryptosporidium</i> spp.	-

* marked products will be launched in 2023