

Vcheck M

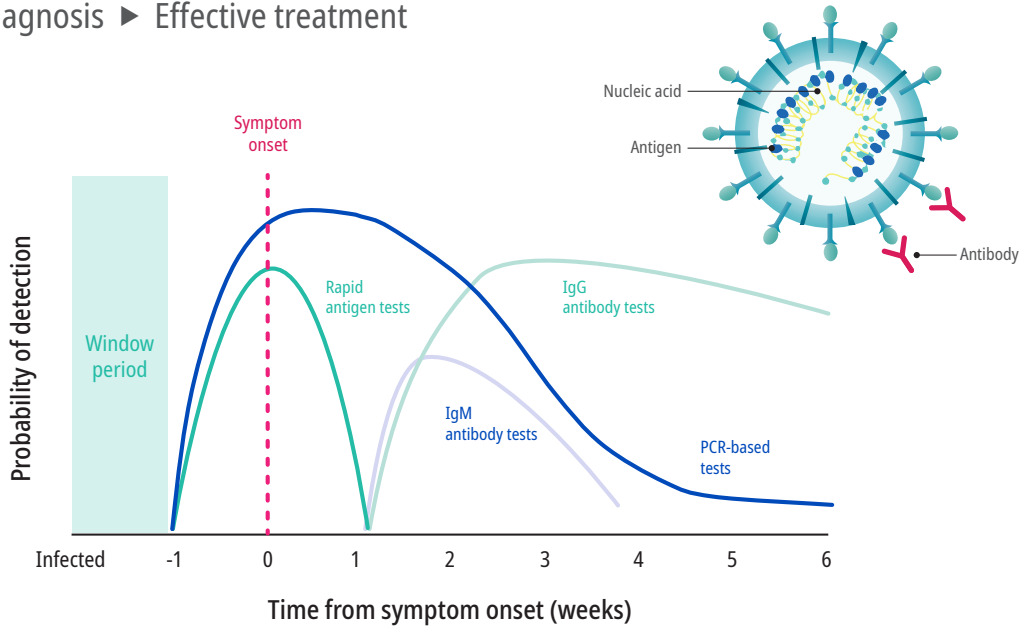
State-of-the-art POC Molecular Diagnostic System



BIONOTE

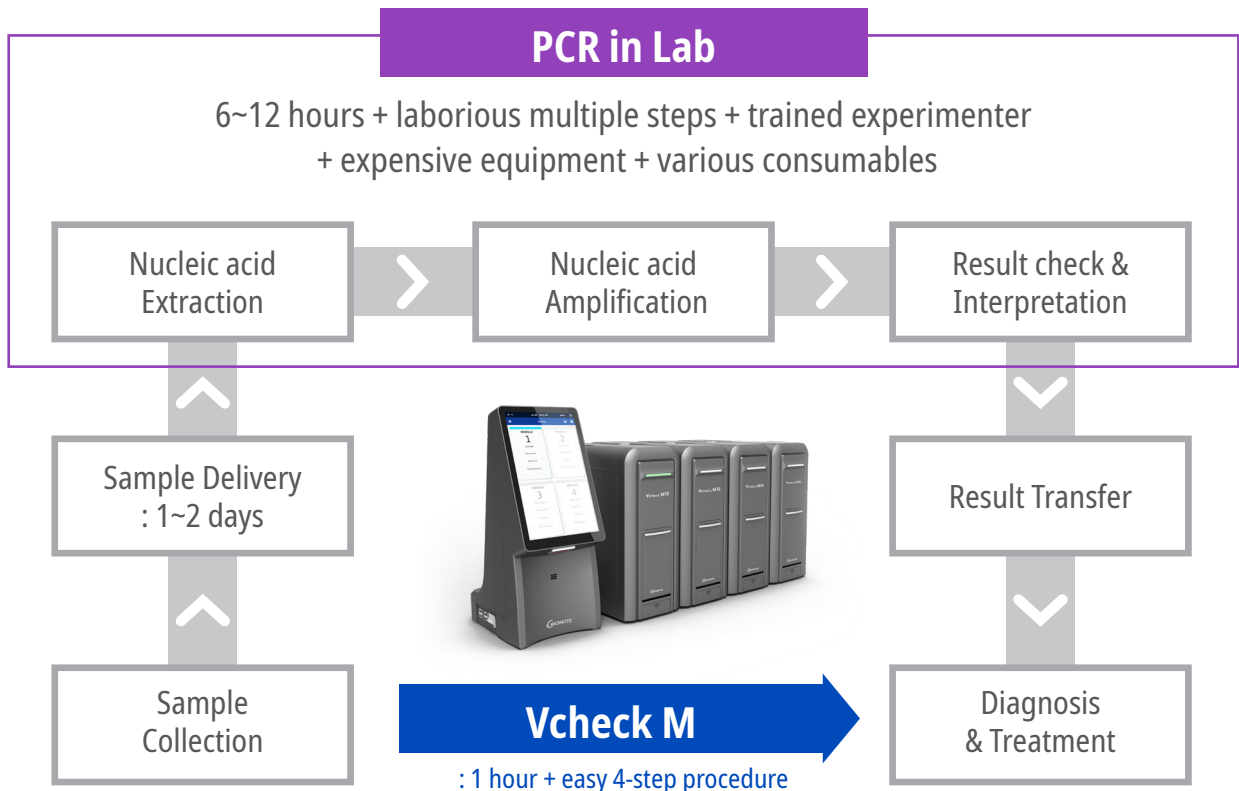
Why PCR?

- 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 8 targets
in a cartridge

Various Setting

Applicable for various species,
sample types, pathogens



Simple Procedure

Automated extraction,
amplification,
and data analysis

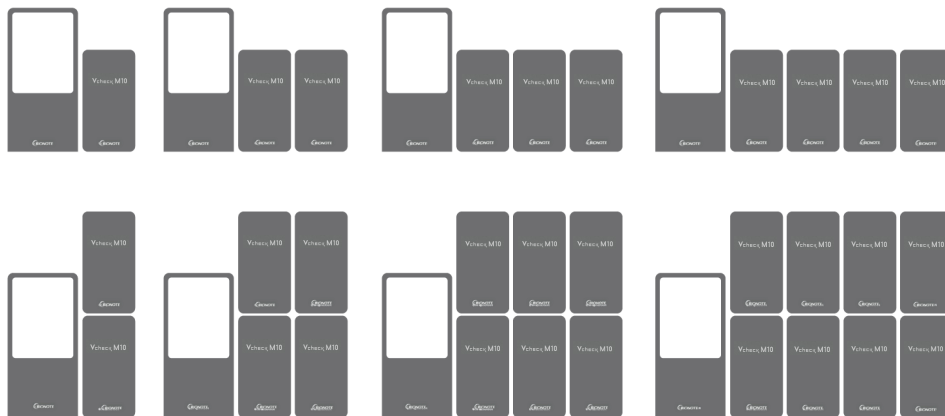
Good Accuracy

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

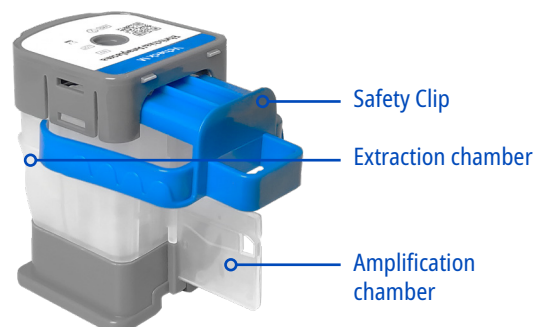
- Minimum maintenance requirements
- Intuitive status indicator
- Compact size
- Easy connection between Modules
- Customized configuration up to 8 modules



Vcheck M Cartridge

All-in-one Cartridge
Multiplex assay up to 8-Plex

- Reliable result by accumulated technologies
- Result in about 1 hour (NA extraction + amplification)
- One-minute hands-on prep
- Multiplex using FAM/HEX/Cy5
- Room temperature storage



Easy 4-step test procedure

1 Scan the sample ID



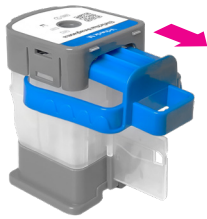
2 Scan the cartridge code



3 Apply the sample & close the cartridge



4 Insert the cartridge



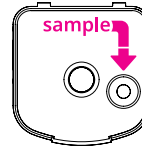
Remove the safety clip



Press down the lid



Dispense the sample



Close the lid

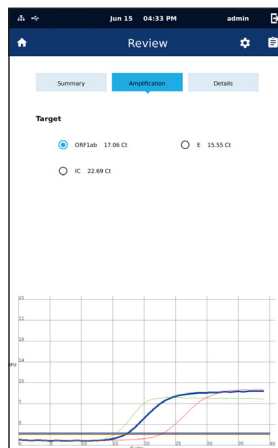
Automatic Result Reading

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

Summary



Amplification



Details



Vcheck M Ehrlichia/Anaplasma

Ehrlichiosis / Anaplasmosis

Pathogen	Clinical signs	Prevalent areas
<i>Ehrlichia canis</i>	Fever, depression, lymphadenopathy, anorexia, weight loss, hair loss, lethargy, bleedings, eye signs	Tropical & temperate areas (USA, Mediterranean, Africa)
<i>Ehrlichia ewingii</i>	Fever, polyarthritits, thrombocytopenia, neurologic disease	USA
<i>Anaplasma phagocytophilum</i>	Fever, lethargy, weight loss, diarrhea, vomiting, seldom bleedings & lameness	Northern hemisphere (Europe, USA, South America, Asia)
<i>Anaplasma platys</i>	Fever, depression, bleeding tendency	Tropical & temperate regions

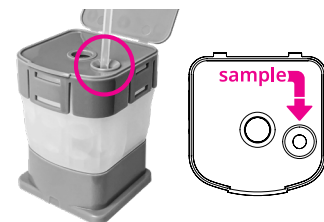
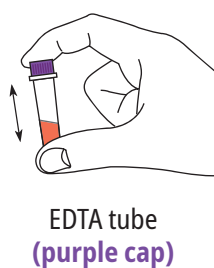
- Diagnosis: Blood smear, CBC, Serum chemistry, Serology, **PCR**

Specification

Purpose	: Detection of <i>Ehrlichia</i> spp. (<i>E. canis</i> & <i>E. ewingii</i>) and <i>Anaplasma</i> spp. (<i>A. phagocytophilum</i> & <i>A. platys</i>)
Species	: Canine, Feline
Sample	: Whole blood (EDTA) 100 µl
Testing Time	: 70 minutes
Storage Temp.	: 2~30 °C
Results	: Qualitative & Semi-quantitative (Ct)
Shelf life	: 12 months
Packing Unit	: 5 Tests/Kit



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



Vcheck M Ehrlichia/Anaplasma

Result Interpretation

Result	Ehrlichia	Anaplasma	Internal Control*
+ Ehrlichia/Anaplasma Positive	+	+	+ / -
+ Ehrlichia Positive	+	-	+ / -
+ Anaplasma Positive	-	+	+ / -
- Ehrlichia/Anaplasma Negative	-	-	+
! Invalid / Re-Test	-	-	-

* Internal Control (IC) can be negative or positive in a positive sample

Performance

- Analytical Sensitivity (LoD)
 - Similar sensitivity compared with existing PCR equipment & reagents

Pathogen	Sample type	LoD (Spiking titer)	Final PCR titer
<i>Ehrlichia</i> spp.	Canine/Feline whole blood	600 copies/rxn	200 copies/rxn
<i>Anaplasma</i> spp.		600 copies/rxn	200 copies/rxn

- Analytical Specificity
 - Interference: No interference for potential interfering substances
 - Cross-reactivity: No cross-reaction with potential cross-reactive substances

No	Substance	Result
1	<i>Borrelia burgdorferi</i>	Negative
2	<i>Bartonella henselae</i>	Negative
3	<i>Leptospira autumnalis</i>	Negative
4	<i>Leishmania infantum</i>	Negative
5	Distemper virus	Negative

No	Substance	Result
6	Adenovirus	Negative
7	Immunodeficiency virus	Negative
8	Leukemia virus	Negative
9	Infectious peritonitis virus	Negative

Vcheck M Babesia gibsoni/canis

Canine Babesiosis

Pathogen	Clinical signs	Prevalent areas
<i>Babesia gibsoni</i>	Fever, lethargy, anorexia, anemia, red urine, splenomegaly, jaundice	Africa, Asia, USA, Southern Europe, Middle East, Australia
<i>Babesia canis canis</i>		Europe
<i>Babesia canis vogeli</i>		Southern Europe, tropical, semitropical regions worldwide
<i>Babesia canis rossi</i>		South Africa

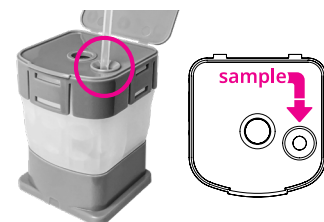
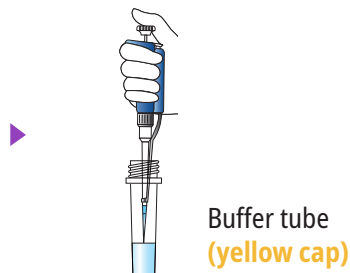
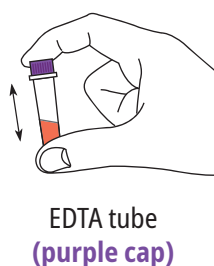
- Diagnosis: Blood smear, CBC, Serum chemistry, Coombs test, Serology, **PCR**

Specification

Purpose	: Detection of <i>Babesia gibsoni</i> and <i>Babesia canis</i> (<i>B. canis canis</i> , <i>B. canis vogeli</i> , <i>B. canis rossi</i>)
Species	: Canine
Sample	: Whole blood (EDTA) 100 µl
Testing Time	: 60 minutes
Storage Temp.	: 2~30 °C
Results	: Qualitative & Semi-quantitative (Ct)
Shelf life	: 12 months
Packing Unit	: 5 Tests/Kit



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



Vcheck M Babesia gibsoni/canis

Result Interpretation

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

* Internal Control (IC) can be negative or positive in a positive sample

Vcheck M Cartridges to be developed (2022)

Vcheck M Canine Vector 8 Panel

No	Target pathogen	Detectable strain	No	Target pathogen	Detectable strain
1	<i>Ehrlichia</i> spp.	<i>E. canis</i> , <i>E. ewingii</i> , <i>E. chaffeensis</i>	5	<i>Rickettsia</i> spp.	<i>R. rickettsii</i>
2	<i>Anaplasma</i> spp.	<i>A. phagocytophilum</i> , <i>A. platys</i>	6	<i>Bartonella</i> spp.	<i>B. henselae</i> , <i>B. koehlerae</i>
3	<i>Babesia</i> spp.	<i>B. gibsoni</i> , <i>B. canis canis</i> , <i>B. canis vogeli</i> , <i>B. canis rossii</i>	7	Canine Hemotropic mycoplasma	<i>M. haemocanis</i>
4	<i>Leishmania</i> spp.	<i>L. infantum</i> , <i>L. donovani</i> , <i>L. mexicana</i>	8	<i>Hepatozoon</i> spp.	<i>H. americanum</i> , <i>H. canis</i>

Vcheck M Canine Anemia 8 Panel

No	Target pathogen	Detectable strain	No	Target pathogen	Detectable strain
1	<i>Ehrlichia</i> spp.	<i>E. canis</i> , <i>E. ewingii</i> , <i>E. chaffeensis</i>	6	<i>Leptospira</i> spp.	<i>L. autumnalis</i> , <i>L. grippotyphosa</i> , <i>L. bratislava</i> , <i>L. pomona</i> , <i>L. canicola</i> , <i>L. icterohaemorrhagiae</i>
2	<i>Anaplasma</i> spp.	<i>A. phagocytophilum</i> , <i>A. platys</i>	7	Canine Hemotropic mycoplasma	<i>M. haemocanis</i>
3	<i>Babesia</i> spp.	<i>B. gibsoni</i> , <i>B. canis canis</i> , <i>B. canis vogeli</i> , <i>B. canis rossii</i>	8	<i>Hepatozoon</i> spp.	<i>H. americanum</i> , <i>H. canis</i>
4	<i>Borrelia</i> spp.	<i>B. burgdorferi</i> , <i>B. afzelii</i> , <i>B. garinii</i>			
5	<i>Rickettsia</i> spp.	<i>R. rickettsii</i>			

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>Anaplasma</i> spp., <i>Babesia</i> spp., <i>Leishmania</i> spp., <i>Rickettsia</i> spp., <i>Bartonella</i> spp., Canine hemotropic mycoplasma (CHM), <i>Hepatozoon</i> spp.	-
Vcheck M Canine Anemia 8 Panel*	<i>Ehrlichia</i> spp., <i>Anaplasma</i> spp., <i>Babesia</i> spp., <i>Borrelia</i> spp. (Lyme disease), <i>Rickettsia</i> spp., <i>Leptospira</i> spp., Canine hemotropic mycoplasma (CHM), <i>Hepatozoon</i> spp.	-
Vcheck M FHV/FCV*	Feline herpesvirus type 1 (FHV-1), Feline calicivirus (FCV)	-
Vcheck M Feline Respiratory 6 Panel*	Feline herpesvirus type 1 (FHV-1), Feline calicivirus (FCV), <i>Mycoplasma felis</i> , <i>Chlamydia felis</i> , Influenza virus, <i>Bordetella bronchiseptica</i>	-
Vcheck M FCoV/FIPV*	Feline coronavirus (FCoV), Feline infectious peritonitis virus (FIPV)	-
Vcheck M Giardia/Trichomonas*	<i>Giardia</i> spp., <i>Trichomonas foetus</i>	-
Vcheck M Feline Diarrhea 8 Panel*	Feline panleukopenia virus (FPV), Feline coronavirus (FCoV), <i>Giardia</i> spp., <i>Trichomonas foetus</i> , <i>Toxoplasma gondii</i> , <i>Salmonella</i> spp., <i>Clostridium perfringens</i> , <i>Cryptosporidium</i> spp.	-
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 FIV/FelV*	FIV, FelV	-
Vcheck M Canine Respiratory 8 Panel*	Canine distemper virus (CDV), Canine adenovirus type 2 (CAV-2), <i>Bordetella bronchiseptica</i> , Canine influenza virus (CIV), Canine parainfluenza virus (CPIV), Canine herpesvirus type 1 (CHV-1), Canine respiratory coronavirus (CRCoV), <i>Mycoplasma cynos</i>	-
Vcheck M AIV Pan/H5/H7/H9*	AIV, AIV H5, AIV H7, AIV H9	-
Vcheck M Feline Anemia 7 Panel*	Feline immunodeficiency virus (FIV), Feline leukemia virus (FeLV), <i>Ehrlichia</i> spp., <i>Anaplasma</i> spp., <i>Bartonella</i> spp., <i>Cytauxzoon felis</i> , Feline hemotropic mycoplasma (FHM)	-
Vcheck M ASFV*	ASFV	-
Vcheck M FMDV Pan/O/A/Asia1*	FMDV, FMDV Type O, FMDV Type A, FMDV Type Asia1	-
Vcheck M Feline Neurologic 6 Panel*	<i>Bartonella</i> spp., <i>Cryptococcus</i> spp., Feline coronavirus (FCoV), <i>Toxoplasma gondii</i> , Feline immunodeficiency virus (FIV), Feline leukemia virus (FeLV)	-
Vcheck M Canine Neurologic 8 Panel*	Canine distemper virus (CDV), <i>Toxoplasma gondii</i> , <i>Neospora</i> spp., <i>Cryptococcus</i> spp., <i>Coccidioides</i> spp., <i>Bartonella</i> spp., <i>Borrelia</i> spp. (Lyme disease), <i>Blastomyces dermatitidis</i>	-

It includes upcoming products. * marked products are scheduled to be released.