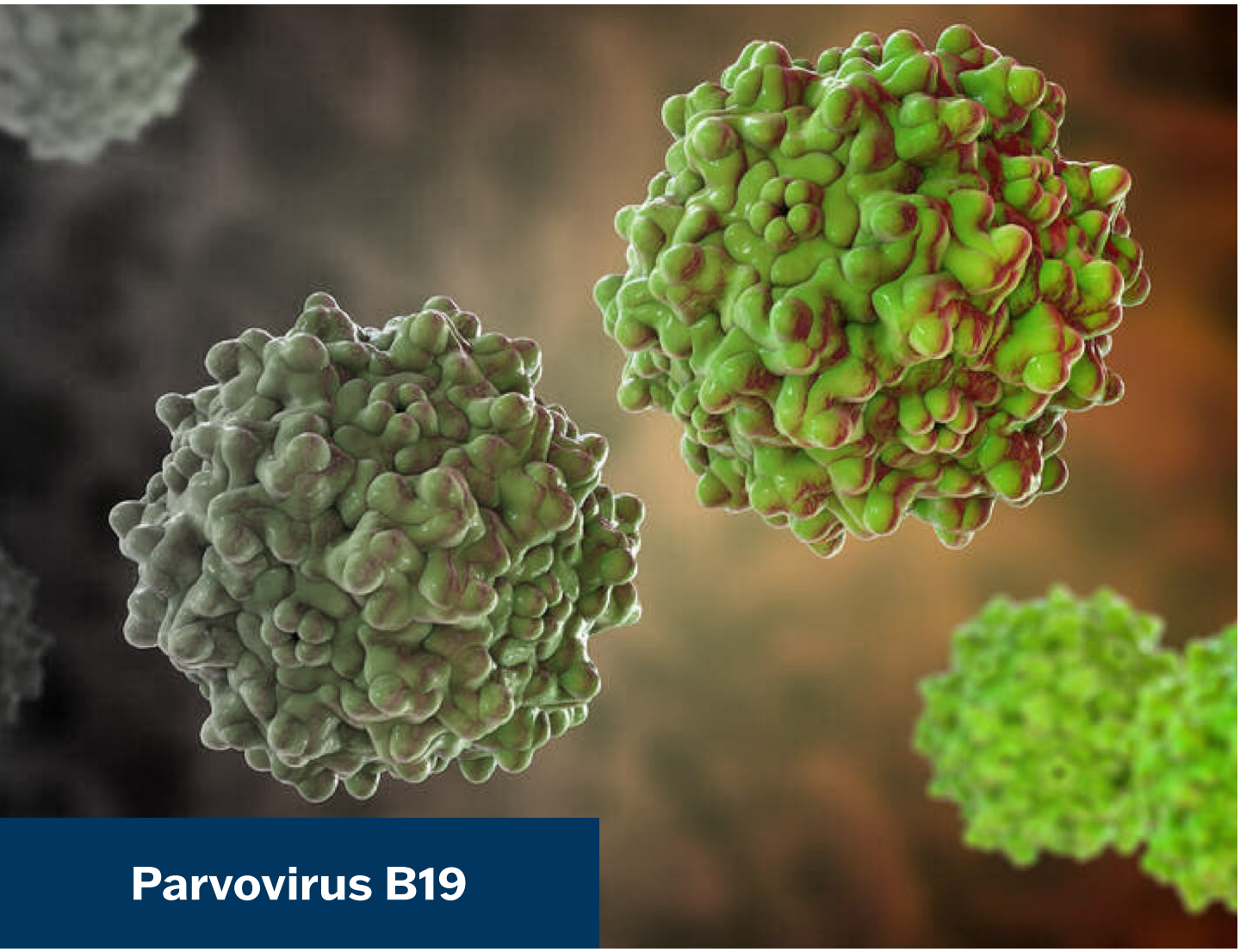


Parvovirus B19

Enzyme immunoassays for the diagnostics of Parvovirus B19 infection

ELISA kits are optimized and validated for detection of IgG and IgM antibodies in human serum or plasma

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Parvovirus B19 (Erythrovirus B19) belongs the Parvoviridae family. It is a common human pathogen. Man is its sole host. It is a non-enveloped single-stranded DNA virus. It consists of two structural proteins, VP1 and VP2, whereas VP2 is the major one and it forms approximately 96% of the total viral particle. Neutralizing antibodies are aimed against VP1.

Infection occurs throughout year with a mild growth at the end of spring. Infection may be transmitted via direct contact with the patient (droplets and even orofaecal transmission), blood derivatives or vertically from the mother to the foetus. Infection occurs in most immunocompetent individuals with no symptoms or with unspecified symptoms of mild upper respiratory tract infection. The virus multiplies in rapidly dividing haematopoietic cells of the bone marrow, and one of the signs may be a slight drop in the blood haemoglobin level.

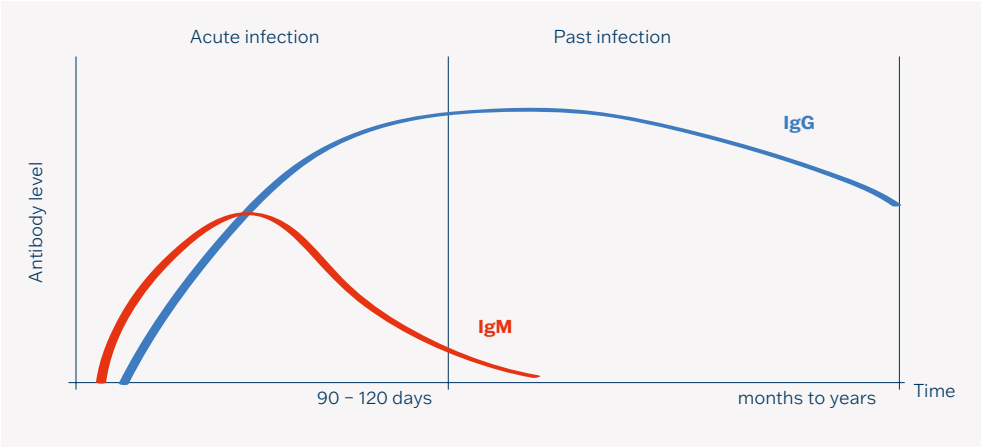
Primary parvovirus B19 infection occurs most frequently in childhood as the so-called fifth disease (erythema infectiosum). The first phase of infection with unspecified symptoms (fever, chills, headache and muscle pain) occurs after an incubation period of 1–2 weeks. Specific manifestations of the disease develop in approximately two weeks (skin exanthema, typical rash in the area of the face, possibly joint pain). Disease may manifest in adults as febrile infection with significant arthralgia. Parvovirus B19 may induce an aplastic crisis in persons with haemolytic diseases. Persistence of infection with manifestations of chronic anaemia may occur in immunocompromised individuals. Primary infection during pregnancy also represents a severe risk. Transplacental transmission of infection occurs approximately in 1/3 of infected pregnant women and may have fatal consequences due to severe anaemia of the foetus (hydrops of the foetus, risk of death of the foetus).

Detection of viral DNA using the PCR method is a method of direct demonstration, determination of specific antibodies in human serum is used for indirect demonstration of the virus. Acute infection typically starts with production of IgM antibodies, which are detectable around the day 10 after the onset of infection, with a peak in two to three weeks, then the IgM antibody levels decrease and persist maximally for 2–3 months. This is followed by an elevation of IgG class antibodies in several days. IgG class antibodies persist for years and usually for the whole life. Prevalence in the population increases with the age, it ranges between 50 and 85% in adults.

Diagnosis of infection

Acute infection typically starts with production of IgM antibodies, which are detectable around the day 10 after the onset of infection, with a peak in two to three weeks, then the IgM antibody levels decrease and persist maximally for 2–3 months. This is followed by an elevation of IgG class antibodies in several days. IgG class antibodies persist for years and usually for the whole life. Prevalence in the population increases with the age, it ranges between 50 and 85% in adults.

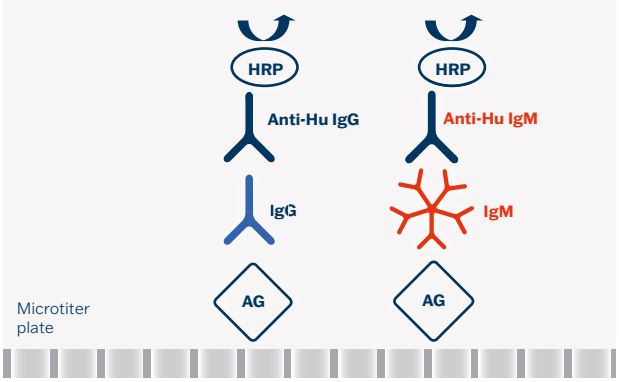
Antibody response



ELISA

Test principle

The assays are based on a sandwich type of ELISA method.



Summary protocol

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 30 min. at 37°C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

VP2 recombinant protein

Clinical application

- Screening test for the detection of specific IgG and IgM antibodies in human serum or plasma
- Checking of therapy results using the semiquantitative determination
- Disease stage diagnosis
- Differential diagnosis of exanthematous diseases

User comfort

- Ready-to-use components; colour-coded components and interchangeable components
- Breakable colour-coded microplate strips
- CUT-OFF included
- Semiquantitative evaluation of results or quantitative evaluation (IU/ml)
- Quantitative evaluation in international units was derived from the international standard WHO (1/602)

Advantages

- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response and Identical assay procedure
- Short total assay time
- Diluent solution of the samples contains RF sorb (EIA Parvovirus B19 IgM)
- Ready for automation
- Possibility of independent verification (CKS)
- Customer support

Test characteristics

ELISA	Diagnostic sensitivity	Diagnostic specificity
EIA Parvovirus IgG	98.6%	99.9%
EIA Parvovirus IgM	96.8%	99.9%

Ordering Information

ELISA

Cat. No.	Product	No. of Tests
PVG096	EIA Parvovirus B19 IgG	96
PVM096	EIA Parvovirus B19 IgM	96
SK-PVG096	SmartEIA Parvovirus B19 IgG	96
SK-PVM096	SmartEIA Parvovirus B19 IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyser.

TestLine®

TestLine Clinical Diagnostics Ltd.
Krizikova 68, 612 00 Brno, Czech Republic
+420 549 121 203
sales@testlinecd.com
www.testlinecd.com

CERTIFIED ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

V09/2022