



SERION ELISA *classic*

# Parvovirus B19 IgG/IgM

## Intended use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum or plasma directed against Parvovirus B19
- Differentiation of acute and past infections

## Diagnostic Efficiency

The SERION ELISA *classic* Parvovirus B19 IgG test was verified in an internal study utilising 230 serum samples from healthy blood donors and pregnant women as well as external quality assessment scheme test sera. The Parvovirus B19 IgG ELISA of a leading European manufacturer was used as the reference test in this study. Sensitivity and specificity of the SERION ELISA *classic* Parvovirus B19 IgM test were assessed by the analysis of 132 serum samples from patients with suspected Parvovirus B19 infection and healthy blood donors using the Parvovirus B19 IgM ELISA of a leading European manufacturer as a reference.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Parvovirus B19 IgG	>99 %	>99 %
SERION ELISA <i>classic</i> Parvovirus B19 IgM	>99 %	>99 %

## Precision

### SERION ELISA *classic* Parvovirus B19 IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.325	4.7	0.352	6.2
Serum 2	1.160	2.7	1.232	4.6
Serum 3	1.381	3.8	1.490	4.0

## SERION ELISA *classic* Parvovirus B19 IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.778	2.1	0.825	1.7
Serum 2	0.981	1.4	1.022	5.3
Serum 3	2.345	1.6	2.358	1.8

### Pathogen

With a diameter of 18–26 nm, the worldwide distributed Parvovirus B19 belongs to the smallest human pathogens. Its capsid is made up of 95 % of the structural protein VP2. The remaining 5 % consists of VP1.

### Disease

In many cases, Parvovirus B19 infections remain clinically asymptomatic. Infected children may develop *erythema infectiosum*, also named fifth disease. After an incubation period of four to 14 days garland-shaped exanthemas spread from the face downwards. The rash, in adults possibly accompanied by arthralgia in the small joints, may last for up to three weeks. Current studies in Germany indicate that 10–20 % of children under three years

of age have already had an infection with the virus. In adults, the seroprevalence increases to 70 %. In pregnant women with primary Parvovirus B19 infection the virus is transmitted to the fetus and may lead to severe complications. In general, the regular course of an infection is limited by the synthesis of neutralizing antibodies. In immunosuppressed patients or patients with chronic haemolytic anaemia, infection may elicit severe clinical consequences with aplastic crisis, which can have fatal consequences.

### Diagnosis

As a consequence of the variable clinical symptoms which may be associated with Parvovirus B19 infection, a clinical diagnosis should be supported by the demonstration of virus specific antibodies.

## Highlights

- Use of virus-like particles (VLPs) composed of recombinant VP2 produced in Baculovirus-infected insect cells
- Sensitive IgM detection for the diagnosis of acute infections
- IgG detection for confirmation of Parvovirus infection and for immune status control, particularly during pregnancy
- Quantitative determination of IgG and IgM antibody activities with IgG results expressed in IU/ml referenced to the international standard of the WHO

Product	Order No.
SERION ELISA <i>classic</i> Parvovirus B19 IgG	ESR122G
SERION ELISA <i>classic</i> Parvovirus B19 IgM	ESR122M

### SERION ELISA *control*

Please visit our website for more information.

### Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19, 97076 Würzburg, Germany  
Tel. +49 931 3045 0 Fax +49 931 3045 100  
Mail [info@serion-diagnostics.de](mailto:info@serion-diagnostics.de) Web [www.serion-diagnostics.de](http://www.serion-diagnostics.de)

virion\serion