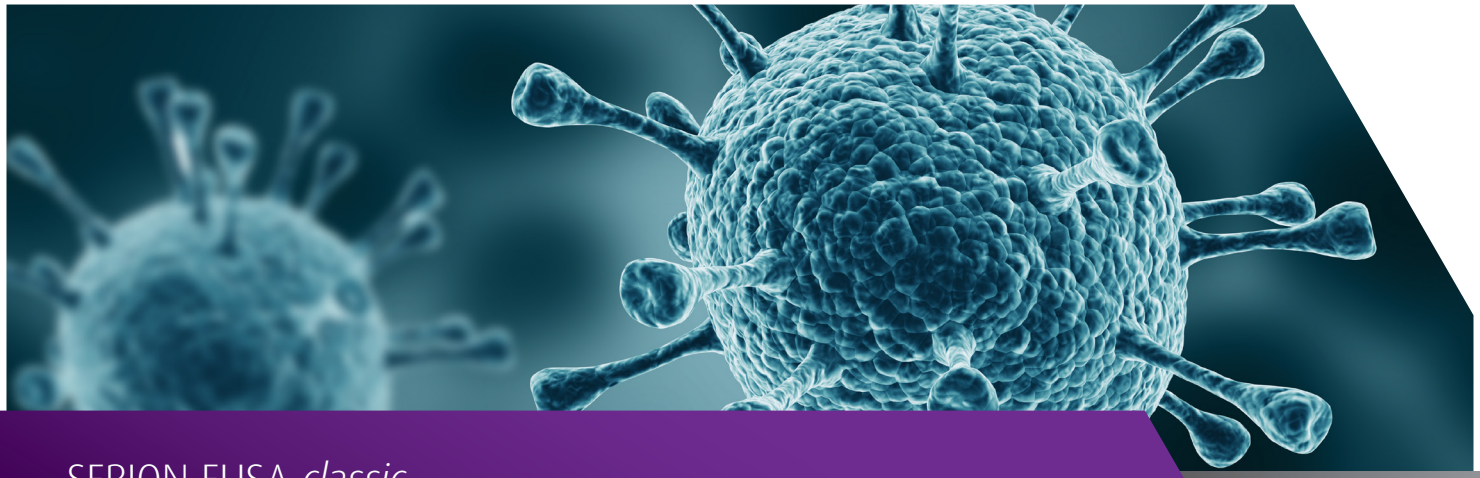

SERION ELISA *classic*

Rubella Virus IgG/IgM

Intended Use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum or plasma directed against Rubella Virus
- Demonstration of IgM antibodies as an initial assay for the detection of acute infections
- Detection of IgG antibodies for the determination of immune status
- Detection of intrathecally produced IgG antibodies in cerebrospinal fluid
- Determination of IgG antibody avidity, by using the corresponding avidity reagent, in order to differentiate between acute and past infections

Diagnostic Efficiency

The SERION ELISA *classic* Rubella Virus IgG was evaluated in an external study by the analysis of 417 serum samples, from patients with suspected Rubella Virus infection, in comparison to various commercially available assays from other manufacturers. The evaluation of SERION ELISA *classic* Rubella Virus IgM was performed by the analysis of 138 serum samples including samples from patients with suspected infection as well as a serum panel from blood donors and pregnant women. Two commercially available ELISA tests were used as a reference.

Product	Sensitivity	Specificity
SERION ELISA *classic* Rubella Virus IgG	99.7 %	>99 %
SERION ELISA *classic* Rubella Virus IgM	>99 %	96.8 %

Precision

SERION ELISA *classic* Rubella Virus IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.403	1.8	0.417	3.6
Serum 2	0.949	3.3	1.057	2.9
Serum 3	1.184	2.0	1.261	2.5

SERION ELISA *classic* Rubella Virus IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.292	2.4	0.317	4.9
Serum 2	0.982	2.9	1.034	3.4
Serum 3	2.036	2.4	2.083	2.9

Pathogen

Rubella Virus is a worldwide distributed human pathogen belonging to the Togavirus family of RNA viruses. It is transmitted by droplet infection.

Disease

Around 50 % of all Rubella Virus infections are asymptomatic and often remain undetected. Following an incubation period of 14 to 21 days a blotchy papular facial rash may appear and spread to the body and extremities. This usually fades after one to three days. Infected children display unspecific symptoms such as snuffles, fever, headache, joint pains and swelling of the lymph nodes in the neck and throat region. With increasing age rare complications may rise, which include arthritis, encephalitis and thrombocytopenia with a resulting tendency to bleeding. Rubella Virus infection during pregnancy may lead to severe damage in the fetus. Consequently, the diagnosis of Rubella during gestation is of considerable importance.

Diagnosis

The detection of IgG antibodies directed against Rubella Virus by ELISA is valuable in determining the immune status. The detection of IgM antibodies is generally indicative of a primary infection, but can also be observed e. g. following reinfections. Due to the severe consequences for the fetus, pregnant women tested positive for IgM antibodies directed against Rubella Virus should be confirmed by additional testings, such as SERION avidity determination.

Highlights

- Sensitive IgM detection as an initial test for the diagnosis of acute infections, particularly during pregnancy
- Demonstration of IgM results expressed in U/ml referenced to the standard sera Leipzig
- Demonstration of IgG antibodies for determination of immune status with results expressed in IU/ml referenced to the international standard of the WHO
- Detection of intrathecally synthesized IgG antibodies for CSF diagnostics
- Differentiation between acute and past infections by determination of IgG antibody avidity using the corresponding avidity reagent
- Sensitive IgM detection in *Dried Blood Spots* (DBS) for demonstration of infections in neonates

Product	Order No.
SERION ELISA *classic* Rublla Virus IgG	ESR129G
SERION ELISA *classic* Rubella Virus IgM	ESR129M
SERION ELISA *avidity reagent* Rubella Virus IgG	B129AVID

SERION ELISA *control*

Please visit our website for more information.

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