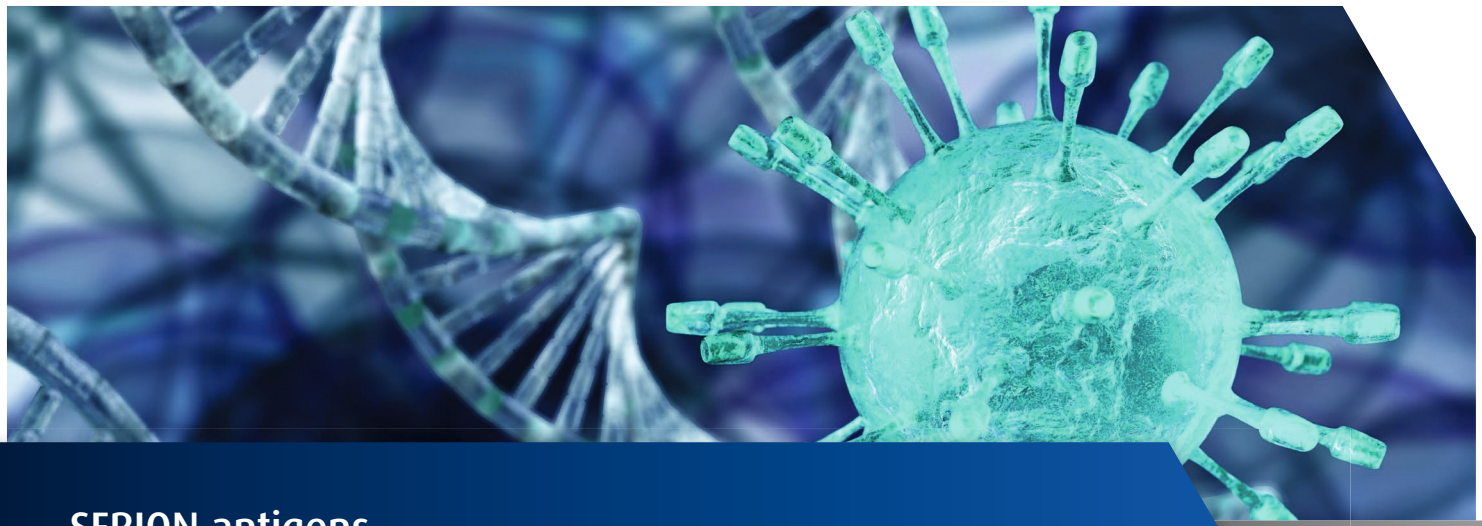

SERION antigens

Rubella Spike Ectodomain (E1-E2) Antigen

SERION Immunologics offers the **first recombinant Rubella Spike Ectodomain (E1-E2) antigen** developed for the **detection of IgG and IgM antibodies.** Its superior performance has been shown in ELISA as well as in bead based immunoassays. Purification from recombinant expression in insect cells in an ISO 13485 certified environment guarantees high quality and lot-to-lot consistency paired with ready availability of bulk quantities.

- ✓ 1st recombinant Rubella antigen for IgM detection
- ✓ ELISA and bead assay approved
- ✓ ISO 13485 certified production environment
- ✓ Capsid-free
- ✓ High specificity
- ✓ Bulk quantities

Background

The widespread Rubella virus belongs to the family of *Matonaviridae*, formerly to *Togaviridae*. It is an enveloped, single-stranded RNA virus with three structural proteins: The capsid protein C interacts with genomic RNA and assembles into the icosahedral nucleocapsid, while the membrane-spanning glycoproteins E1 and E2 form the viral spike complexes. The E1-E2 heterodimers on the viral surface are the major target for neutralizing antibodies during infection.

Rubella virus is transmitted by droplets. In populations with low vaccination uptake rates, the majority of infections occur in children. While severe complications in children are rare, Rubella virus infection during pregnancy can cause congenital rubella syndrome with serious damage to fetuses. Consequently, the diagnosis of Rubella infection during gestation is of considerable importance.

Specific IgM detection is essential for reliable Rubella diagnostics. Unfortunately, many Rubella IgM assays show significant cross-reactivity towards other pathogens. It is believed that the capsid protein C is primarily responsible for these non-specific interferences in Rubella assays.

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Product Description

The new **Rubella Spike Ectodomain (E1-E2) antigen** complements the growing SERION Immunologics raw material portfolio for IVD assay development. It is a capsid-free, highly pure recombinant antigen produced in insect cells in a patented process. The sequence of the recombinant protein is derived from the Rubella vaccine strain HPV-77 and combines the ectodomains of glycoproteins E1 and E2, which are the major immunological targets. The sequence and the eukaryotic expression system were carefully chosen to provide a reliable product for the development of highly specific IgG and IgM detection assays.

Order Information and Related Products

Code	Description	Packaging
BA129R01 ***NEW!***	Rubella Spike Ectodomain (E1-E2) Antigen, recombinant	1 mg
MAB129.001/002	Anti-Rubella Virus monoclonal antibody IgM, clone B16B11F8 / A7A11H3	1 mL
MAB129.001H/002H	Anti-Rubella Virus monoclonal antibody IgM, clone B16B11F8 / A7A11H3, in human matrix	1 mg
PLS129G	Rubella Virus IgG positive defibrinated human plasma	1 mL
PLS129M	Rubella Virus IgM positive defibrinated human plasma	1 mL

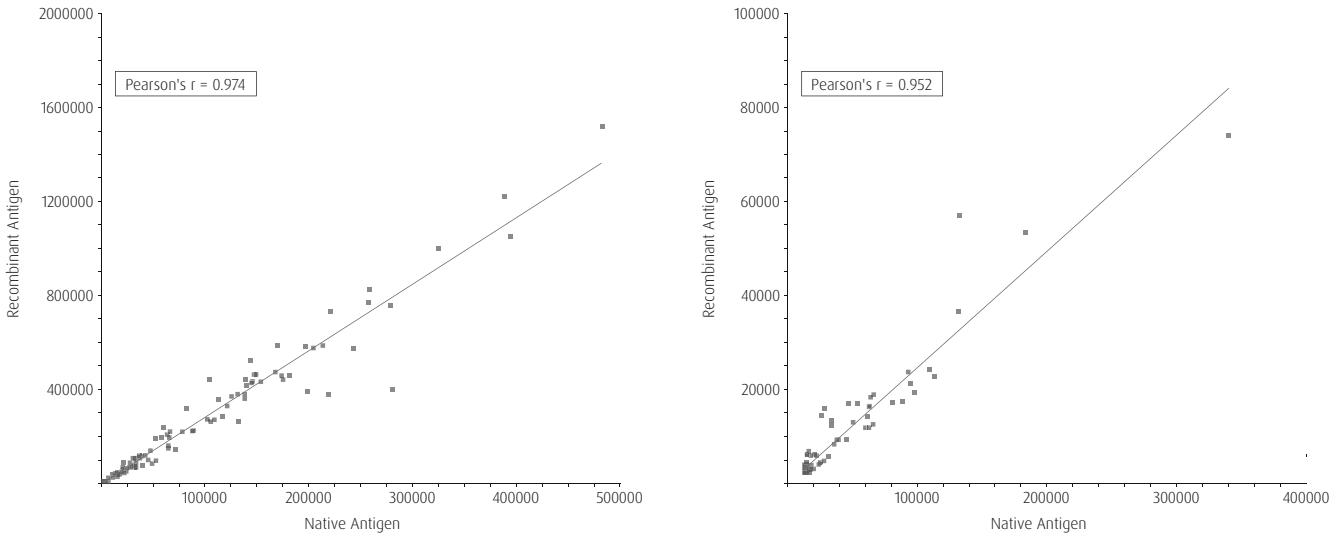
Experimental Data

High correlation between the recombinant Rubella Spike Ectodomain (E1-E2) antigen and a commercial native Rubella virus antigen

The new recombinant Rubella Spike Ectodomain (E1-E2) antigen and a commercially available native Rubella virus antigen were both coupled on magnetic particles in a bead assay setup for the detection of Rubella IgG or IgM antibodies. The quantitative comparison of the measurement results of more than 100 samples analyzed with both bead couplings showed very high correlation coefficients (r > 0.95). These data disclose the new recombinant Rubella Spike Ectodomain (E1-E2) antigen as a very well suited candidate to replace native Rubella antigens in serological IVD assays.

Figure 1: Quantitative comparison of measurement results for >100 Rubella IgG (left) or IgM (right) positive and negative samples. The samples were analyzed using magnetic particles coupled with a commercial native Rubella virus antigen or with the recombinant Rubella Spike Ectodomain (E1-E2) antigen. Pearson correlation coefficient was calculated for both analyses: r = 0.974 (IgG) and r = 0.952 (IgM).

Correlation of Rubella IgG (left) and IgM (right) antibody detection with recombinant and native Rubella virus antigens



Superior diagnostic performance of IgG and IgM detection assays using the new Rubella Spike Ectodomain (E1-E2) antigen

Rubella Spike Ectodomain (E1-E2) antigen was coated on microtiter plates (ELISA) and coupled on magnetic particles (bead assay) for the detection of Rubella IgG or IgM antibodies in mixed sample panels containing positive and negative patient sera. Very high sensitivity and specificity rates were achieved with both assay setups, when measurement results were compared with commercially available Rubella IgG and IgM IVD assays (see tabel 1). The quantitative analysis of both, IgG and IgM detection, proved a clear discrimination of positive and negative samples as shown in figure 2 for the bead assay setup with the new Rubella Spike Ectodomain (E1-E2) antigen.

Rubella IgG	Sensitivity	Specificity
ELISA	100 %	100 %
Bead assay	100 %	100 %

Rubella IgM	Sensitivity	Specificity
ELISA	100 %	94.6 %
Bead assay	100 %	100 %

Table 1: Method comparison of ELISA or bead-based assay using Rubella Spike Ectodomain (E1-E2) antigen for coating or coupling, respectively. 50 Rubella IgG positive or negative samples were measured with both setups and compared to the results obtained with a commercial Rubella IgG IVD assay. For Rubella IgM, 75 positive or negative samples were analyzed and compared with the consensus results of two commercial Rubella IgM IVD assays.

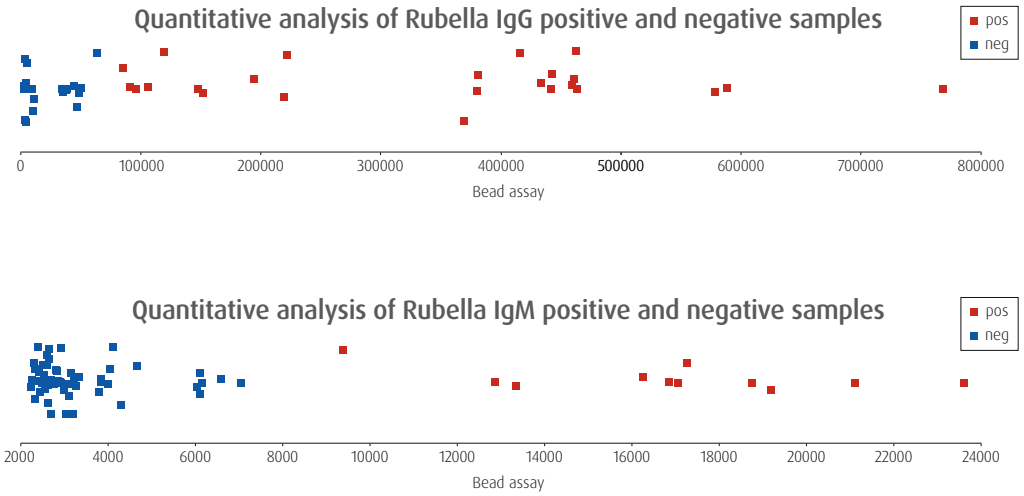


Figure 2: Quantitative analysis of measurement results for 50 Rubella IgG and 75 Rubella IgM positive or negative samples with the bead assay setup coupled with Rubella Spike Ectodomain (E1-E2) antigen. The samples were evaluated positive (red) or negative (blue) with commercial Rubella IgG and IgM IVD assays as reference.

The new Rubella Spike Ectodomain (E1-E2) antigen allows IgG and IgM detection with high precision

Intra-assay analyses of Rubella IgG and IgM positive samples show very precise measurement results with low CVs (coefficient of variation) in the ELISA as well as in the bead based assay, using Rubella Spike Ectodomain (E1-E2) antigen for antibody detection.

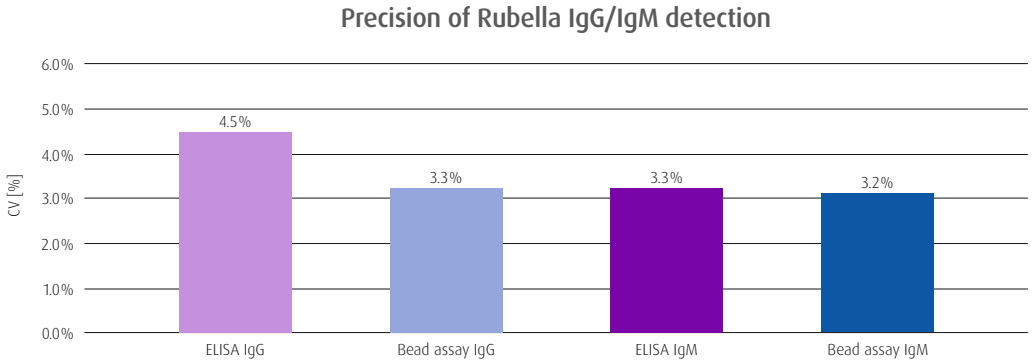


Figure 3: 94 replicates of a Rubella IgG and a Rubella IgM positive samples were analyzed using microtiter plates (ELISA, violet) or magnetic particles (bead assay, blue) coated or coupled with Rubella Spike Ectodomain (E1-E2) antigen. The % CVs were calculated for measurement results of IgG or IgM detection with each assay.

Matching monoclonal antibodies for the development of Rubella IgM controls

Two clones of humanized monoclonal Rubella IgM antibodies efficiently bind the new Rubella Spike Ectodomain (E1-E2) antigen with a very high reactivity compared to patient samples. Both clones show the same titration performance as high positive patient sera, but with higher reactivity – even after pre-dilution. They are an excellent alternative to disease state serum for the development of IVD assay controls, as their humanized Fc part allows the detection with anti-human IgM antibodies. Both clones are available in cell culture supernatant (order no. MAB129.001 and MAB129.002) or human serum matrix (order no. MAB129.001H and MAB129.002H).

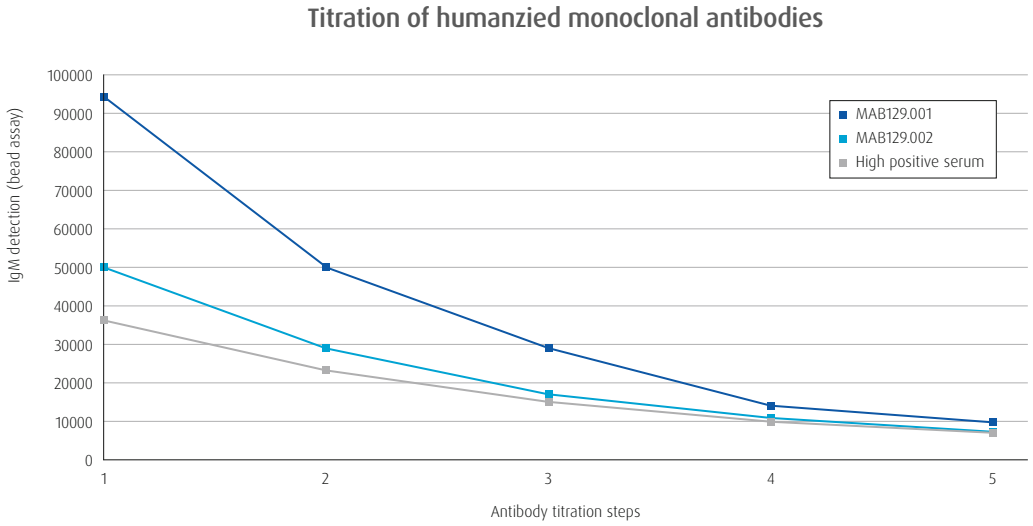


Figure 4: Two humanized monoclonal Rubella IgM antibodies (MAB129.001 and MAB129.002) and a high positive Rubella IgM serum were titrated in 5 steps from 1:100 to 1:12800 and measured using magnetic particles coupled with Rubella Spike Ectodomain (E1-E2) antigen. The two monoclonal antibodies were pre-diluted 1:8 (MAB129.001) or 1:2 (MAB129.002), respectively.

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