Clinical significance: The pathogenic agent of rubella is the rubella virus, which is present worldwide. It is a positive single-stranded, enveloped RNA virus and the only species belonging to the genus Rubivirus of the Togaviridae family. The rubella virus was first isolated in 1962 by Parkman, Weller and Neva. There are 2 genotypes, which are divided into further subgenotypes. The rubella genotype I (RGI) occurs in the western hemisphere, whereas the rubella genotype II (RGII) is mainly found in Asia.

A rubella infection is transmitted by aerosols. It is considered contagious already during the incubation period of two to three weeks. Typical symptoms are headache, lymph node swellings, particularly in the neck area, and a blotchy exanthema, which generally persists for 3 days. This generalised, macular, non-confluent, light red exanthema spreads from the face to the trunk and the extremities in a postauricular manner. A known complication is arthritis in the finger, hand, elbow and ankle joints, which may last for up to 3 weeks in adults. Further complications are myocarditis, neuritis, otitis, bronchitis and, very rarely, rubella encephalitis with a good prognosis. The majority of infections occur between the ages of 5 to 14 years and lead to life-long immunity. An infection spread of 80 to 90% is assumed for adulthood in central Europe. This means that 10 to 20% of women of child-bearing age are not immune.

Rubella virus transmitted diaplacentaly during the first trimester of pregnancy causes the highest rate of embryonic deformities. Severe forms of rubella embryopathy are found in around 80% of cases. In the foreground are Gregg’s Triad consisting of heart deformations, eye defects and hearing damage such as congenital vitium cordis in around 48%, retinopathy in around 39%, cataract/myopia in around 29%, glaucoma in around 3%, and deafness in around 39%, congenital vitium cordis in around 48%, retinopathy in around 39%, cataract/myopia in around 29%, glaucoma in around 3%, and deafness in around 39%, congenital vitium cordis in around 48%, retinopathy in around 39%, cataract/myopia in around 29%, glaucoma in around 3%, and deafness in around 39%, congenital vitium cordis in around 48%, retinopathy in around 39%, cataract/myopia in around 29%, glaucoma in around 3%, and deafness in around 39%, congenital vitium cordis in around 48%, retinopathy in around 39%, cataract/myopia in around 29%, glaucoma in around 3%, and deafness in around 39%, congenital vitium cordis in around 48%, retinopathy in around 39%, cataract/myopia in around 29%, glaucoma in around 3%, and deafness in around 39%. In many countries, an acute rubella infection is considered to be a medical indication for termination of pregnancy. Various inoculation strategies have been employed worldwide to prevent rubella infections. Since active immunization is well tolerated, vaccination programs aim to protect all young persons before puberty using a two-stage rubella vaccination.

Application of the Anti-Rubella Virus ELISA: Laboratory investigations using serological methods as the haemaggulination inhibition (HAI) test or ELISA play a key role in the diagnosis of acute rubella infections. An increase in antibody titer within 10 days or the presence of IgM antibodies indicates an acute infection. It must, however, be taken into consideration that anti-rubella IgM antibodies may be present months after an infection. Therefore, the antibody avidity of specific IgG antibodies is investigated to determine the time period of infection (order no. EI 2590-9601-1 G). Low-avidity IgG antibodies with an avidity index of under 40% are present for only a few weeks after an acute rubella infection.

Suspected cases of rubella virus-induced encephalitis should be verified by the investigation of an intrathecal synthesis of antibodies against rubella virus in the cerebrospinal fluid (CSF). For this therapy-relevant application EUROMMUN offers an Anti-Rubella Virus ELISA developed specifically for CSF diagnostics (order no. EI 2590-9601-L G).

According to medical guidelines for infectious serological care in pregnant women (German Federal Committee of Doctors and Health Insurance, 1995) the rubella immune status should be investigated serologically as early as possible in the pregnancy. Women without sufficient immunological protection should receive special consultation and should be serologically monitored during pregnancy. The ELISA technique is the method of choice for analysing large patient panels, as in pregnancy diagnostics, due to its speed and ease of use. This technique is superior to haemaggulination insofar as it allows the separate determination of specific IgG and IgM antibodies, as well as the analysis of low-avidity IgG antibodies.
**EUROIMMUN AG · D-23560 Luebeck (Germany) · Seekamp 31 · Phone +49 451 5855-0 · Fax 5855-591 · E-mail euroimmun@euroimmun.de · www.euroimmun.de

** CV2 partial protein, which only contains the

Currently not available as IVD in the EU.

thyrotropin (TSH)
free thyroxine (FT4)
free triiodothyronine (FT3)
Hormone determination:
thyroglobulin (TG)
Antigen determination:
tyrosine phosphatase (IA2; IgG)
P/Q calcium channel* (VGCC; IgG)
insulin (IAA; IgG)
glutamic acid decarboxylase (GAD; IgG)
acetylcholine receptor (ACHR; IgG)
TSH receptor (IgG)
thyroglobulin (TG; IgG)
thyroid peroxidase (TPO; IgG)

** Test Characteristics Anti-Rubella Virus ELISA (IgG)

Reproducibility: Coefficients of variation (CVs) were determined using data from three sera with values at different points on the standard curve. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on 4 measurements performed in six different test runs on at least two different days.

Reference range: The levels of anti-rubella virus antibodies (IgG) were analysed with the EUROIMMUN ELISA in a panel of 500 healthy blood donors. With a cut-off value of 10IU/ml, 94% of blood donors were found to carry the known infection positive virus (IgG), in agreement with the known infection level in adults.

Determination of the immune status after vaccination or wild-type infection: The Robert Koch Institute in Berlin, Germany states that an antibody titer of 15IU/ml and above indicates good immunity against rubella virus.

** Comparison with HIT: Antibody concentrations were determined in 191 sera from patients with suspected rubella infection (Laboratory Prof. Enders, Stuttgart, Germany) using the EUROIMMUN Anti-Rubella Virus ELISA and the HIT (Laboratory Prof. Enders). The correlation of qualitative results obtained with both tests was 100%.

** Quality assessment data: A total of 196 sera from different quality assessment providers (IN instant e.V., Germany; Labquality, Finland; MQ, Switzerland; NEQUAS, UK) was analysed using the EUROIMMUN Anti-Rubella Virus ELISA. The results were 100% in agreement with the quality assessment target values.

Antibody concentrations were determined in 192 sera from patients with suspected rubella infection (Laboratory Prof. Enders, Stuttgart, Germany) using the EUROIMMUN Anti-Rubella Virus ELISA.

** Technical data:**

**Antigen:** Highly purified cell lysate from Vero cells infected with the Rubella virus strain HPV-77.

**Calibration:** Quantitative, in international units per millilitre (IU/ml) using the international reference preparation NIBSC RUBI-1-94 (1 st international standard for anti-rubella virus immunoglobulin, National Institute for Biological Standards and Control, Hertfordshire, UK).

**Calibration serum: 1:1000, 1:100, 1:10, 1:1, 1:0.1, 1:0.01, 1:0.001**

**Serum and sample dilution:** Sample or plasma: 1:101 in sample buffer.

**Reagents:** Ready for use, with the exception of the wash buffer (10x).

**Measurement:** Colour-coded solutions, in most cases exchangeable with those in international reference preparation NIBSC RUBI-1-94, 1:1000, 1:100, 1:10, 1:1, 1:0.1, 1:0.01, 1:0.001.

**Kit format:** 96 break-off wells. Kit includes all necessary reagents.

**Order no.:** E1 2590-9601 G

---

EUROIMMUN

ImmunoBlots

Autoantibody determination: EUROASSAY

Test procedure: 30 min / 30 min / 15 min. Room temperature. Fully automatable.

Measurement: 450 nm. Reference wavelength between 620 nm and 650 nm.

Kit format: 96 break-off wells. Kit includes all necessary reagents.

Order no.: E1 2590-9601 G

---

**EUROIMMUN**

Antigen

Currently not available as IVD in the EU.

**CV2 partial protein, which only contains the

Currently not available as IVD in the EU.

thyrotropin (TSH)
free thyroxine (FT4)
free triiodothyronine (FT3)
Hormone determination:
thyroglobulin (TG)
Antigen determination:
tyrosine phosphatase (IA2; IgG)
P/Q calcium channel* (VGCC; IgG)
insulin (IAA; IgG)
glutamic acid decarboxylase (GAD; IgG)
acetylcholine receptor (ACHR; IgG)
TSH receptor (IgG)
thyroglobulin (TG; IgG)
thyroid peroxidase (TPO; IgG)

**Test Characteristics Anti-Rubella Virus ELISA (IgG)**

Reproducibility: Coefficients of variation (CVs) were determined using data from three sera with values at different points on the standard curve. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on 4 measurements performed in six different test runs on at least two different days.

Reference range: The levels of anti-rubella virus antibodies (IgG) were analysed with the EUROIMMUN ELISA in a panel of 500 healthy blood donors. With a cut-off value of 10IU/ml, 94% of blood donors were found to carry the known infection positive virus (IgG), in agreement with the known infection level in adults.

Determination of the immune status after vaccination or wild-type infection: The Robert Koch Institute in Berlin, Germany states that an antibody titer of 15IU/ml and above indicates good immunity against rubella virus.

**Comparison with HIT:** Antibody concentrations were determined in 191 sera from patients with suspected rubella infection (Laboratory Prof. Enders, Stuttgart, Germany) using the EUROIMMUN Anti-Rubella Virus ELISA and the HIT (Laboratory Prof. Enders). The correlation of qualitative results obtained with both tests was 100%.

**Quality assessment data:** A total of 196 sera from different quality assessment providers (IN instant e.V., Germany; Labquality, Finland; MQ, Switzerland; NEQUAS, UK) was analysed using the EUROIMMUN Anti-Rubella Virus ELISA. The results were 100% in agreement with the quality assessment target values.

Antibody concentrations were determined in 192 sera from patients with suspected rubella infection (Laboratory Prof. Enders, Stuttgart, Germany) using the EUROIMMUN Anti-Rubella Virus ELISA.

**Technical data:**

**Antigen:** Highly purified cell lysate from Vero cells infected with the Rubella virus strain HPV-77.

**Calibration:** Quantitative, in international units per millilitre (IU/ml) using the international reference preparation NIBSC RUBI-1-94 (1 st international standard for anti-rubella virus immunoglobulin, National Institute for Biological Standards and Control, Hertfordshire, UK).

**Calibration serum: 1:1000, 1:100, 1:10, 1:1, 1:0.1, 1:0.01, 1:0.001**

**Serum and sample dilution:** Sample or plasma: 1:101 in sample buffer.

**Reagents:** Ready for use, with the exception of the wash buffer (10x).

**Measurement:** Colour-coded solutions, in most cases exchangeable with those in international reference preparation NIBSC RUBI-1-94, 1:1000, 1:100, 1:10, 1:1, 1:0.1, 1:0.01, 1:0.001.

**Kit format:** 96 break-off wells. Kit includes all necessary reagents.

**Order no.:** E1 2590-9601 G

---

EUROIMMUN

ImmunoBlots

Autoantibody determination: EUROASSAY

Test procedure: 30 min / 30 min / 15 min. Room temperature. Fully automatable.

Measurement: 450 nm. Reference wavelength between 620 nm and 650 nm.

Kit format: 96 break-off wells. Kit includes all necessary reagents.

Order no.: E1 2590-9601 G