Anti-Rubella Virus ELISA (IgG)

- Based on antigens from the rubella virus strain HPV-77
- Quantification in international units (IU/ml) for assessment of the immune status
- Fully automatable processing and evaluation

**Technical data**

**Antigen**
Highly purified cell lysate from vero cells infected with the rubella virus strain HPV-77

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

- Calibration serum 1: 200 IU/ml
- Calibration serum 2: 50 IU/ml
- Calibration serum 3: 10 IU/ml
- Calibration serum 4: 1 IU/ml

Recommended upper limit for non-infected persons (cut-off): 10 IU/ml

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

**Reagents**
Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA test kits

**Testablauf**
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 number**
EI 2590-9601 G

**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. A rubella infection is transmitted by aerosols. Typical symptoms are headache, lymph node swellings, particularly in the neck area, and a blotchy generalised exanthema which typically persists for 3 days. Complications can be transient arthritis in the joints, myocarditis, neuritis, otitis, bronchitis and very rarely rubella encephalitis with a good prognosis. It is assumed that 80% to 95% of adults in Central Europe have immunity to rubella virus from natural infection or vaccination. This means that 5% to 20% of women of child-bearing age are susceptible to infection. Rubella virus can be transmitted diaplacentally in the first 3 months of pregnancy, causing severe embryopathies in 80% of cases. The predominant manifestations are heart disorders, eye defects and hearing damage (Gregg's syndrome). Psychomotoric retardation (e.g. in connection with microcephaly), neonatal purpura with hepatosplenomegaly, diabetes mellitus, spontaneous abortion or death of the newborn are also documented.

**Diagnostic application**

Infections with rubella virus can be diagnosed by detection of specific antibodies of classes IgG and IgM. An increase in the IgG antibody titer within 10 days or the presence of IgM antibodies indicates an acute infection. A positive IgM test in pregnancy requires clarification using another test method (determination of avidity of specific IgG antibodies, IgG immunoblot, if necessary PCR or viral culture from chorion biopsy material or amniotic fluid or analysis of foetal blood). The IgM diagnostics can be optimised by using the Anti-Rubella Virus Glycoprotein ELISA (IgM). This test helps to minimise unspecific reactions and cross reactions with antibodies against other infectious agents, which occasionally occur in ELISAs based on viral lysate or in indirect immunofluorescence tests.
Reference range

The levels of anti-rubella virus antibodies were analysed with the EUROIMMUN ELISA in a panel of pregnant women, vaccinated children and healthy blood donors (n=838, origin: Germany). With a cut-off value of 10 IU/ml, 94% of the blood donors were anti-rubella virus positive (IgG), in agreement with the known infection level in adults.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using three sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 4 determinations performed in 6 different test runs.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Intra-assay variation, n = 20</th>
<th>Inter-assay variation, n = 4 x 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean value (IU/ml)</td>
<td>CV (%)</td>
</tr>
<tr>
<td>1</td>
<td>7</td>
<td>4.6</td>
</tr>
<tr>
<td>2</td>
<td>37</td>
<td>3.9</td>
</tr>
<tr>
<td>3</td>
<td>147</td>
<td>4.7</td>
</tr>
</tbody>
</table>

Specificity and sensitivity

192 clinically characterised patient samples from a mixed panel (pregnant women, vaccinated children of 1 to 10 years old, healthy blood donors) were investigated with the EUROIMMUN Anti-Rubella Virus ELISA (IgG). The specificity was 100% and the sensitivity 97.8% with respect to another commercially available ELISA.

Quality assessment data

318 clinically characterised patient samples (INSTAND, NEQAS, Labquality, MQ and RfB) were investigated with the EUROIMMUN Anti-Rubella Virus ELISA (IgG). The specificity was 100% at a sensitivity of 99.6%.

Comparison with HAI

Antibody concentrations were determined in 191 sera from patients with suspected rubella virus infections (Laboratory Prof. Enders, Stuttgart, Germany) using the EUROIMMUN Anti-Rubella Virus ELISA (IgG) and the haemagglutination inhibition (HAI) assay of Prof. Enders. There was 100% agreement between the qualitative results of the two tests.

<table>
<thead>
<tr>
<th>n = 191</th>
<th>HAI Prof. Enders</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>positive</td>
</tr>
<tr>
<td>EUROIMMUN Anti-Rubella Virus ELISA (IgG)</td>
<td>180</td>
</tr>
<tr>
<td></td>
<td>negative</td>
</tr>
</tbody>
</table>

* The result from 2 negative sera was confirmed with the Virion/Serion ELISA classic. One serum was borderline.