Rubella Virus IgM μ-capture ELISA

Enzyme immunoassay for the qualitative determination of IgM-class antibodies against Rubella Virus in human serum.

REF RE57091

Σ 96

2-8°C

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1. INTRODUCTION

Rubella is an enveloped RNA virus belonging to the togaviruses. It has a spherical shape measuring about 50-70 nm in diameter. There appears to be only one antigenic type, and no cross-reactivity with alphaviruses or other members of the togavirus group has been found. Rubella viruses are pathogens of the respiratory tract and transmitted mainly by droplet infection. Rubella is a worldwide common contagious disease with mild constitutional symptoms and a generalized rush. But when it occurs during pregnancy, there is a significant risk of severe damage to the fetus. The risk of congenital rubella depends primarily on the month of pregnancy in which infection is acquired: overall, app. 16% of infants have major defects at birth following maternal rubella in the first 3 months of pregnancy. Congenital rubella infection may lead to a syndrome with single or multiple organ involvements, known as embryopathia rubellosa. In some cases infection is inapparent but results in consequential damages as eye defects, deafness, growth retardation, and others. Naturally acquired immunity usually is long-lasting, but reinfection is possible due to decreasing levels of circulating antibodies. For immunization a vaccine containing live virus is used.

<table>
<thead>
<tr>
<th>Species</th>
<th>Disease</th>
<th>Symptoms</th>
<th>Mechanism of infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rubella</td>
<td>acquired rubella (german measles)</td>
<td>generalized rush (fever, nausea)</td>
<td>Transmission by close person-to-person contact, spread most probably by droplets via the respiratory tract</td>
</tr>
<tr>
<td>Virus</td>
<td>congenital rubella syndrome (Embryopathia rubellosa)</td>
<td>Cardiovascular lesions, eye defects, hearing impairment, CNS involvement and others</td>
<td>fetal infection: transmission by hematogenous spread during maternal viremia</td>
</tr>
</tbody>
</table>

Infection may be identified by
- Detection of virus by PCR (prenatal)
- Hemagglutination inhibition (HAI), Haemolysis-in-gel test (HiG)
- Detection of antibodies by EIA, ELISA

Measurement of antibodies in the serum is important for the determination of the immune status. Even a previous infection though rather overt may not yield a long-lasting immunity, but may result in an antibody titer too low to prevent reinfection. Especially the screening of adolescents and young women should be a mandatory routine in prenatal care.

2. INTENDED USE

The IBL Rubella Virus IgM µ-capture-ELISA is intended for the qualitative determination of IgM class antibodies against Rubella Virus IgM in human serum.

3. PRINCIPLE OF THE ASSAY

The qualitative immunoenzymatic determination of IgM-class antibodies against Rubella Virus is based on the ELISA (Enzyme-linked Immunosorbent Assay) technique. The Rubella Virus IgM ELISA is an IgM µ-capture ELISA. The plates are coated with anti-human IgM. After washing the wells to remove all unbound sample material horseradish peroxidase labelled Rubella virus antigen conjugate is added. This conjugate binds to the captured Rubella-specific antibodies. The immune complex formed by the bound conjugate is visualized with Tetramethylbenzidine (TMB) substrate which gives a blue reaction product. The intensity of this product is proportional to the amount of Rubella-specific IgM antibodies in the specimen. Sulfuric acid is added to stop the reaction. This produces a yellow endpoint colour. Absorbance at 450 nm is read using an ELISA microwell plate reader.

4. MATERIALS

4.1. Reagents supplied

- **Microtiterplate (IgM):** 12 breakapart 8-well snap-off strips coated with anti-human IgM-class antibodies; in resealable aluminium foil.
- **Sample Diluent***: 1 bottle containing 100 ml of ready to use buffer for sample dilution; pH 7.2 ± 0.2; coloured yellow; white cap.
- **Stop Solution:** 1 bottle containing 15 ml ready to use sulfuric acid, 0.5 mol/l; red cap.
- **Washing Solution (20x conc.)*:** 1 bottle containing 50 ml of a 20-fold concentrated buffer for washing the wells; pH 7.2±0.2; white cap.
- **Conjugate****: 1 vial containing 12 ml conjugate, ready to use, coloured yellow, black cap.
- **TMB Substrate:** 1 vial containing 15 ml 3,3',5,5'-tetra-methyl-benzidine (TMB); ready to use, yellow cap.
- **Rubella Virus IgM Cut-Off Control****:** 1 vial containing 3 ml; coloured yellow; Ready to use; green cap.
- **Rubella Virus IgM Positive Control****:** 1 vial containing 2 ml; coloured yellow; Ready to use; red cap.
- **Rubella Virus IgM Negative Control****:** 1 vial containing 2 ml; coloured yellow; Ready to use; blue cap.
  * contains 0.1 % Bronidox L after dilution
  ** contains Thimerosal
  *** contains 0.1 % Kathon
  **** contains 0.02% Bronidox L and 0.02% Kathon

4.2. Materials supplied

- **1 Strip holder**
- **1 Cover foil**
- **1 Test protocol**

4.3. Materials and Equipment needed

- **ELISA microwell plate reader, equipped for the measurement of absorbance at 450/620nm**
- **Incubator 37°C**
- **Manual or automatic equipment for rinsing wells**
- **Pipettes to deliver volumes between 10, 100 and 1000 µl**
- **Vortex tube mixer**
- **Deionised or (freshly) distilled water**
- **Disposable tubes**
- **Timer**
5. STABILITY AND STORAGE

The reagents are stable up to the expiry date stated on the label when stored at 2...8 °C.

6. REAGENT PREPARATION

It is very important to bring all reagents, samples and controls to room temperature (20...25°C) before starting the test run!

6.1. Coated Snap-off Strips

The ready to use breakapart snap-off strips are coated with anti-human IgM-class antibodies. Store at 2...8°C. Immediately after removal of strips, the remaining strips should be resealed in the aluminium foil along with the desiccant supplied and stored at 2...8 °C; stability until expiry date.

6.2. Conjugate

The vial contains 12 ml of a horseradish peroxidase conjugate, buffer and stabilizers. The conjugate is ready to use and has to be stored at 2...8°C. After first opening stability until expiry date when stored at 2...8°C.

6.3. Controls

The control vials contain ready to use control solutions with stabilizers and preservatives. It has to be stored at 2...8°C. After first opening stability until expiry date when stored at 2...8°C.

6.4. Sample Diluent

The bottle contains 100ml phosphate buffer, stabilizers and preservatives. This ready to use solution has to be stored at 2...8°C. After first opening stability until expiry date when stored at 2...8°C.

6.5. Washing Solution (20x conc.)

The bottle contains 50ml of a concentrated buffer, detergents, stabilizers and preservatives. Dilute washing solution 1+19; e.g. 5 ml washing solution + 95 ml fresh and germ free redistilled water. The diluted buffer will keep for at 5 days if stored at room temperature. Crystals in the solution disappear by warming up to 37 °C in a water bath. After first opening the concentrated washing solution is stable until expiry date when stored at 2...8°C.

6.6. TMB Substrate Solution

The bottle contains 15 ml of a tetramethylbenzidine/hydrogen peroxide system. The reagent is ready to use and has to be stored at 2...8°C, away from the light. The solution should be colourless or could have a slight blue tinge. If the substrate turns into blue, it may have become contaminated and should not be used for the test performance After first opening stability until expiry date when stored at 2...8°C.

6.7. Stop Solution

The bottle contains 15 ml 0.2 M sulphuric acid solution (R 36/38, S 26). This ready to use solution has to be stored at 2...8°C. After first opening stability until expiry date.

7. SPECIMEN COLLECTION AND PREPARATION

Use human serum samples with this assay. If the assay is performed within 5 days after sample collection, the specimen should be kept at 2...8°C; otherwise they should be aliquoted and stored deep-frozen (-70 to -20°C). If samples are stored frozen, mix thawed samples well before testing. Avoid repeated freezing and thawing. Heat inactivation of samples is not recommended.

7.1. Sample Dilution

Before assay, all samples should be diluted 1+100 with Sample Diluent. Dispense 10µl sample and 1ml Sample Diluent into tubes to obtain a 1+100 dilution and thoroughly mix with a Vortex.

8. ASSAY PROCEDURE

8.1. Test Preparation

Please read the test protocol carefully before performing the assay. Result reliability depends on strict adherence to the test protocol as described. The following test procedure is only validated for manual procedure. If performing the test on ELISA automatic systems we recommend to increase the volume of washing solution from 300µl to 350µl to avoid washing effects. Prior to commencing the assay, the distribution and identification plan for all specimens and controls should be carefully established on the result sheet supplied in the kit. Select the required number of microtiter strips or wells and insert them into the holder.

Please allocate at least:

<table>
<thead>
<tr>
<th>Wells</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 well</td>
<td>(e.g. A1) for the substrate blank,</td>
</tr>
<tr>
<td>1 well</td>
<td>(e.g. B1) for the negative control,</td>
</tr>
<tr>
<td>2 wells</td>
<td>(e.g. C1+D1) for the cut off control and</td>
</tr>
<tr>
<td>1 well</td>
<td>(e.g. E1) for the positive control</td>
</tr>
</tbody>
</table>

Controls and patient samples should be determined in duplicate.

Perform all assay steps in the order given and without any appreciable delays between the steps. A clean, disposable tip should be used for dispensing each control and sample.

Adjust the incubator to 37° ± 1°C.

1. Dispense 100µl controls and diluted samples into the respective wells. Leave well A1 for substrate blank.
2. Cover wells with the foil supplied in the kit.
3. Incubate for 1 hour ± 5 min at 37±1°C.
4. When incubation has been completed, remove the foil, aspirate the content of the wells and wash each well three times with 300µl of washing solution. Avoid overflows from the reaction wells. The soak time between each wash cycle should be minimum 5 sec. At the end carefully remove remaining fluid by tapping strips on tissue paper prior to the next step!

Note: Washing is critical! Insufficient washing results in poor precision and falsely elevated absorbance values.
5. Dispense 100µl conjugate into all wells except for the blank well (e.g. A1). Cover with foil.
6. Incubate for 30 min 37±1°C.
7. Repeat step 4.
8. Dispense 100µl TMB Substrate Solution into all wells
9. Incubate for exactly 30 min at room temperature (20...25°C) in the dark.
10. Dispense 100µl Stop Solution into all wells in the same order and at the same rate as for the TMB substrate solution.
    Any blue colour developed during the incubation turns into yellow.
11. Measure the absorbance of the specimen at 450/620nm within 30 min after addition of the stop solution.

8.2. Measurement
Adjust the ELISA Microwell Plate Reader to zero using the substrate blank in well A1.

If - due to technical reasons - the ELISA reader cannot be adjusted to zero using the substrate blank in well A1, subtract the absorbance value of well A1 from all other absorbance values measured in order to obtain reliable results!

Measure the absorbance of all wells at 450 nm and record the absorbance values for each control and patient sample in the distribution and identification plan.

Dual wavelength reading using 620 nm as reference wavelength is recommended.

If applicable calculate the mean absorbance values of all duplicates.

9. RESULTS

9.1. Calculation of Results
The abundance of Rubella IgM is expressed as cut off index (COI) and is calculated as follows (use not more than one decimal to express the abundance):

Rubella IgM abundance = \frac{\text{(mean) absorbance of control or patient specimen}}{\text{mean absorbance of cut-off control}} = \text{COI (cut off index)}

COI x 10 = \text{U (Units)}

9.2. Run Validation Criteria
In order for an assay to be considered valid, the following criteria must be met:

- **Substrate blank** in A1: Absorbance value < 0.100.
- **Negative control** in B1: Absorbance value < cut-off
- **Cut-off control** in C1 and D1: Absorbance value 0.150 – 1.30.
- **Positive control** in E1: Absorbance value > cut-off.

If these criteria are not met the test run is not valid and has to be repeated.

9.3. Interpretation of Results
Samples are considered **positive** if the abundance is higher than 11 U.

Samples with an abundance between 9 and 11 U can not be considered as clearly positive or negative

→ **grey zone**

It is recommended to confirm the results by testing the sample again in duplicate. If results in the second test are again in the grey zone a second serum sample should be tested and judged for a change in result.

Samples are considered **negative** if the abundance is lower than 9 U.

10. SPECIFIC PERFORMANCE CHARACTERISTICS

10.1. Precision
Different samples containing different levels of the parameter determined, were assayed to assess repeatability and reproducibility of the assay (Intraassay and Interassay CV%).

<table>
<thead>
<tr>
<th>Interssay</th>
<th>n</th>
<th>Mean (U)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pos. Serum</td>
<td>3(48)</td>
<td>28.4</td>
<td>10.3</td>
</tr>
<tr>
<td>Pos. Serum</td>
<td>3(54)</td>
<td>25.3</td>
<td>11.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intraassay</th>
<th>n</th>
<th>Mean (OD)</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pos. Serum</td>
<td>23</td>
<td>1.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Pos. Serum</td>
<td>24</td>
<td>1.1</td>
<td>4.0</td>
</tr>
</tbody>
</table>

10.2. Diagnostic Specificity
The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. Diagnostic Specificity was assessed by testing 59 sera specimen from population to be positive and negative for IgM. 51/52 sera were observed negative. It is 98 %.

10.3. Diagnostic Sensitivity
The diagnostic sensitivity is defined as the probability of the assay of scoring positive in the presence of the specific analyte. Diagnostic sensitivity was assessed by testing 59 sera specimen from population to be positive and negative for IgM. 8/7 sera were observed positive. It is 100%

10.4. Interferences
Interferences with hemolytic or lipemic sera are not observed.

10.5. Cross Reactivity
Cross reactivity with the different serum samples containing antibodies to Parvovirus, Chagas, Trichinella, Helicobacter, Toxoplasmosis, Mumps, EBV, TBE, Dengue virus, Mycoplasma and Bordetella is not observed.
11. LIMITATIONS OF THE PROCEDURE

Bacterial contamination or repeated freeze-thaw cycles of the specimen may affect the absorbance values. Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.

12. PRECAUTIONS AND WARNINGS

- In compliance with article 1 paragraph 2b European directive 98/79/EC the use of the in vitro diagnostic medical devices is intended by the manufacturer to secure suitability, performances and safety of the product. Therefore the test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The use of the testkits with analyzers and similar equipment has to be validated. Any change in design, composition and test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes. The manufacturer is not liable for false results and incidents for these reasons. The manufacturer is not liable for any results by visual analysis of the patient samples.
- Only for in-vitro diagnostic use.
- All components of human origin used for the production of these reagents have been tested for anti-HIV antibodies, anti-HCV antibodies and HBsAg and have been found to be non-reactive. Nevertheless, all materials should still be regarded and handled as potentially infectious.
- Do not interchange reagents or strips of different production lots.
- No reagents of other manufacturers should be used along with reagents of this test kit.
- Do not use reagents after expiry date stated on the label.
- Use only clean pipette tips, dispensers, and lab ware.
- Do not interchange screw caps of reagent vials to avoid cross-contamination.
- Close reagent vials tightly immediately after use to avoid evaporation and microbial contamination.
- After first opening and subsequent storage check conjugate and control vials for microbial contamination prior to further use.
- To avoid cross-contamination and falsely elevated results pipette patient samples and dispense conjugate without splashing accurately to the bottom of wells.
- The NovaLisa™ ELISA is only designed for qualified personnel who are familiar with good laboratory practice.

WARNING: Sulphuric acid irritates eyes and skin. Keep out of the reach of children. Upon contact with the eyes, rinse thoroughly with water and consult a doctor!

12.1. Disposal Considerations

Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.

BIBLIOGRAPHY

SCHEME OF THE ASSAY
Rubella Virus IgM µ-capture ELISA

Test Preparation

Prepare reagents and samples as described.
Establish the distribution and identification plan for all specimens and controls on the result sheet supplied in the kit.
Select the required number of microtiter strips or wells and insert them into the holder.

Assay Procedure

<table>
<thead>
<tr>
<th></th>
<th>Substrate blank (e.g. A1)</th>
<th>Negative control</th>
<th>Positive control</th>
<th>Cut-off control</th>
<th>Sample (diluted 1+100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative control</td>
<td></td>
<td>100µl</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Positive control</td>
<td>-</td>
<td>-</td>
<td>100µl</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Cut-off control</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100µl</td>
<td>-</td>
</tr>
<tr>
<td>Sample (diluted 1+100)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>100µl</td>
</tr>
</tbody>
</table>

Cover wells with foil supplied in the kit
**Incubate for 1 h at 37°C**
Wash each well three times with 300µl of washing solution

<table>
<thead>
<tr>
<th></th>
<th>Conjugate</th>
<th>Negative control</th>
<th>Positive control</th>
<th>Cut-off control</th>
<th>Sample (diluted 1+100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative control</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
</tr>
</tbody>
</table>

Cover wells with foil supplied in the kit
**Incubate for 30 min 37±1°C**
Wash each well three times with 300µl of washing solution

<table>
<thead>
<tr>
<th></th>
<th>TMB Substrate</th>
<th>Negative control</th>
<th>Positive control</th>
<th>Cut-off control</th>
<th>Sample (diluted 1+100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMB Substrate</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
</tr>
</tbody>
</table>

**Incubate for exactly 30 min at room temperature in the dark**

<table>
<thead>
<tr>
<th></th>
<th>Stop Solution</th>
<th>Negative control</th>
<th>Positive control</th>
<th>Cut-off control</th>
<th>Sample (diluted 1+100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop Solution</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
<td>100µl</td>
</tr>
</tbody>
</table>

Photometric measurement at 450 nm (reference wavelength: 620 nm)
<table>
<thead>
<tr>
<th>REF</th>
<th>Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Λοτο n.: / Αριθμός -Παραγωγή:</td>
</tr>
<tr>
<td>Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρήσιμος περιόδης από:</td>
<td></td>
</tr>
<tr>
<td>CONC</td>
<td>Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα</td>
</tr>
<tr>
<td>LYO</td>
<td>Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Λυοφιλισμένο</td>
</tr>
<tr>
<td>LVD</td>
<td>In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Equipamiento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.</td>
</tr>
<tr>
<td>Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluación. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης.</td>
<td></td>
</tr>
<tr>
<td>Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Leggere le istruzioni prima dell’uso. / Διαβάστε τις οδηγίες πριν την χρήση.</td>
<td></td>
</tr>
<tr>
<td>Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l’abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άµεση επαφή µε το φως του ηλίου.</td>
<td></td>
</tr>
<tr>
<td>Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:</td>
<td></td>
</tr>
<tr>
<td>Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγό:</td>
<td></td>
</tr>
<tr>
<td>Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!</td>
<td></td>
</tr>
</tbody>
</table>

Symbols of the kit components see MATERIALS SUPPLIED.

Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.

Voir MATERIEL FOURNI pour les symbôles des composants du kit.

Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.

Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.

Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.

Για τα σύµβολα των συστατικών του κιτ συµβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

### IBL AFFILIATES WORLDWIDE

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</tr>
</thead>
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<td>Fax: -1704</td>
<td><a href="mailto:IBL@IBL-Transatlantic.com">IBL@IBL-Transatlantic.com</a></td>
</tr>
</tbody>
</table>

**LIABILITY**: Complaints will only be accepted in written and if all details of the test performance and results are included (complaint form available from IBL or supplier). Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement. Regardless, in the event of any claim, the manufacturer’s liability is not to exceed the value of the test kit. Any damage caused to the kit during transportation is not subject to the liability of the manufacturer.

Symbols Version 3.5 / 2008-10-01