

Product Name: RUBELLA BR2S ANTIGEN

Catalogue Number: EL-05-15

Storage: Store this antigen preparation frozen at - 70 °C to - 100 °C. Repeated freezing and thawing should be avoided.

Hazards: The product has been inactivated. No test method guarantees a product to be non-infectious. All products should be handled as if potentially infectious. Generally accepted good laboratory practices appropriate to biological reagents should be employed when handling this product.

Strain: HPV-77

Cultured In: Vero cells, an established cell line from African Green Monkey Kidney.

Buffer: NTE buffer (Sodium chloride, TRIS and EDTA)

Agent Description: Rubella causes a mild rash illness of children and adults known as German measles. There is often pharyngitis and enlargement of the cervical lymph nodes. Infection often occurs during childhood with many infections being asymptomatic and complications being rare. However, infection of women in the first 16 weeks of pregnancy can lead to congenital defects developing in the foetus such as cataracts, nerve deafness and cardiac abnormalities. Antibody in women of childbearing age protects the foetus from being infected and thereby prevents congenital abnormalities from developing.

Rubella virus is classified as a toga virus. It is immunologically distinct from other known viruses. The virus particle is spherical with a diameter of 60 - 70 nm and contains a single strand of RNA in a nucleocapsid surrounded by a lipid envelope. It has three structural proteins; E1 and E2, which are associated with the viral envelope and C which forms the nucleocapsid with RNA. E1 is reactive with IgM and IgG antibodies and is the antigen responsible for haemagglutination activity. E2 and C induce IgG antibodies but E1 is most important to antibody testing.

Preparation: Vero cells infected with Rubella release virus particles into the culture supernatant. Supernatant is harvested and clarified. The clarified material is then concentrated and purified by sucrose gradient centrifugation.

Inactivation: Rubella BR2S antigen is inactivated by UV irradiation and confirmed by double passage assay on Vero cells.

Description: The predominant form of the antigen is whole virions suspended in NTE with sucrose. The preparation is free of detergent. Residual non-viral protein may come from host tissue and culture medium.

Recommendations for Use: This antigen preparation should be sonicated immediately prior to use to ensure that the preparation is uniform. This preparation may be used as is in a variety of immunoassay formats including micro well ELISA, latex agglutination and IgM detection assays. This product is suitable for those assay formats which require the purest of antigens.

Quality Control Information

Product Name: Rubella BR2S Antigen

Lot Number: 05XXXXX

It is important that each user perform titrations of antigen using their own assay as each assay format and serum release panel makes different performance demands on the antigen. Often, use of an antigen may be optimized by making adjustments to concentrations of other assay reagents such as conjugate. Once this is complete the result is cost effective use of the antigen and optimal assay performance.

Tests:

Specific Activity: This is defined as activity (ELISA titration - Microbix Technical Bulletin number 93-1.) per unit protein concentration (BioRad micro assay). Specific activity of the product is compared to that of the reference antigen and reported as a percentage of reference.

Result: XXX % of reference antigen

Protein Concentration: Protein is determined using the BioRad dye binding assay in the micro assay format. The standard curve is generated with a known concentration of IgG.

Result: XXX mg/mL

Inactivation Assay: Rubella inactivation is assessed using a double passage assay in tissue culture. The preparation is considered inactivated when no plaques are observed at second passage.

Result: Negative

Quality Assurance Signature:

Date:



Assistance: If you have any questions regarding the production, testing or use of this antigen, please send them by email to customer.service@microbix.com or fax 905-361-8911, with any relevant data, to Microbix Technical Services. Your complete satisfaction with the performance of this product is important to us.