



**Microbix Biosystems Inc.**

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*Product Name:*

## Rubella K0S Concentrate Antigen

*Catalogue Number:* EL-05-13

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

*Hazards:* We are aware of no specific hazards associated with this product. The reagent has been inactivated and should contain no infectious material. 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 fetus such as cataracts, nerve deafness and cardiac abnormalities. Antibody in women of childbearing age protects the fetus from being infected and thereby prevents congenital abnormalities from developing.

Rubella virus is classified as a togavirus. 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 material is then concentrated.

*Inactivation:* Rubella K0S Concentrate antigen is inactivated by exposing the material to UV light. This method was chosen to maximize loss of infectivity with a minimum loss of antigenicity.

*Description:* This preparation is high in both Rubella titre and specific activity. The predominant form of the antigen is whole virions suspended in NTE buffer. The preparation is free of detergent. Residual non-viral protein comes 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 microwell ELISA and IgM detection assays. It is particularly well suited for coating on solid phase for IgG detection and for IgM capture assay formats.

*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](mailto: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.

## Quality Control Information

*Product Name:* Rubella K0S Concentrate Antigen

*Lot Number:* 05307A1

Microbix performs quality control tests to ensure each batch meets in-house specifications. Test results are provided with each lot of antigen shipped. Antigen users require this information for a number of reasons:

- to maintain a record for good manufacturing purposes,
- to correlate user results with Microbix results and
- for use as a starting point for those just starting with either a new antigen or developing a new assay.

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.

### *Test:*

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

*Result:* 0.59 mg/ml

*Inactivation Assay:* Test antigen is inoculated onto monolayers. Potentially infected monolayers are then overlaid with a semisolid medium. These are incubated 6 days and are overlaid with semisolid medium containing neutral red dye. On the seventh day, the monolayers are examined for plaques. One live virus particle is capable of developing a plaque. The preparation is considered inactivated when no plaques are observed.

*Result:* No plaque detected



Quality Assurance Signature:

25-February, 2010