

Product Name: *Mycoplasma pneumoniae* grade 3 Antigen

Catalogue Number: EL-11-03

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

Hazards:

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: FH

Cultured In: Broth base medium.

Buffer: Phosphate based buffer containing non-ionic detergent and a sugar based stabilizer

Agent Description: Gram-negative pleomorphic cells, spherical to ovoid shaped, single tripled-layered membrane, but lacking true cell wall. Causes lower respiratory infections; less often a pharyngitis progressing to bronchitis or pneumoniae; gradual onset with headache, malaise, paroxysmal cough, substernal pain; leucocytosis in some cases. Duration varies from a few days to a month or more. Low fatality.

Preparation: Mycoplasma organisms are harvested by centrifugation, washed in PBS and extracted using non-ionic detergent-containing buffer.

Inactivation: Detergent inactivation by lysis.

Description: The resulting antigen preparation contains soluble Mycoplasma components suspended in a detergent and sugar-containing phosphate buffer.

Recommendations for Use: This antigen preparation should be mixed by vortexing immediately prior to use to ensure that the preparation is uniform. Do not sonicate the material. This preparation may be used in a variety of immunoassay formats or may be further purified to meet the needs of a particular assay format. Grade 3 antigen may be widely used for both IgG and IgM detection in assays which include EIA with polystyrene and latex solid phases.

Quality Control Information

Product Name: *Mycoplasma pneumoniae* grade 3 Antigen

Lot Number: 11XXXXX

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.

Tests:

Titre: This antigen preparation is titrated using a micro titre plate based ELISA. Antigens are tested for reactivity with IgG. The dilution of antigen which generates a signal of 1.0 O.D. unit in the immunoassay is compared to that of the standard approved antigen. The result of this comparison is expressed as a percentage of the reference.

IgG Result: XXX %

Protein Concentration: Total protein concentration that includes *Mycoplasma pneumoniae* proteins and residual cell culture proteins 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: The effectiveness of inactivation is determined when no detection of growth is detected in two blind passages under the original culture conditions.

Result: No growth detected

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.