MICROBIX

Product Information Sheet

***Product Name*:** *Chlamydia trachomatis* grade 2 Antigen

***Catalogue Number*:** EL-12-02

***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: *Chlamydia trachomatis* LGV type II strain 434

Cultured In: Mouse L cells

Buffer: Phosphate buffered saline pH 7.2

Agent Description: *Chlamydia trachomatis* is a non-motile gram negative intracellular bacterium, which has two forms during replication. The extracellular form, used in antigen preparations, is the elementary body. It has a diameter of 0.25 - 0.35 μm. The intracellular form is the reticulate or initial body which is 0.25 - 1 μm in diameter. Although *Chlamydia trachomatis* is antigenically complex only a few antigens are important in diagnostic testing. Sixty percent of the dry weight of the outer membrane of the elementary body is composed of major outer membrane protein (MOMP). MOMP is a transmembrane protein with type, species and genus reactive epitopes. It possesses an epitope used to characterize *C. trachomatis* into 15 serotypes or serovars. The outer membrane of *C. trachomatis* has a heat stable lipopolysaccharide antigen (LPS) with 2-keto-3-deoxyoctonic acid as an immuno-dominant component. This antigen contains the reactive epitopes employed in genus specific serological tests. There is structural similarity and antigenic cross reactivity between chlamydial and other gram negative LPS moieties.

Preparation: Mouse L cells are infected with *C. trachomatis* elementary bodies. Optimally infected cells are harvested and disrupted by sonication in PBS. Cellular debris is removed using centrifugation.

Inactivation: This antigen preparation is inactivated using gamma radiation. This procedure is effective primarily by damaging chlamydial genetic material.

Description: *Chlamydia trachomatis* grade 2 antigen contains a high concentration of elementary bodies and chlamydial components in PBS. The preparation contains no preservative or detergent. Residual host cellular material is present.

Recommendations for Use: Chlamydia antigen 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 or may be further purified to meet the needs of a particular assay format. Grade 2 antigen is widely used for both IgG and IgM detection in assays which include EIA with polystyrene and latex solid phases and M capture formats.

Quality Control Information

Product Name: *Chlamydia trachomatis* grade 2 Antigen *Lot Number:* 12XXXXX

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:

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: The effectiveness of inactivation is tested by inoculating an L cell monolayer with antigen. The culture is manipulated using the original optimal culture conditions used to manufacture the antigen. The culture is monitored for cytopathic effect for 5 days. If no sign of infection is observed the culture is passaged into a fresh monolayer. The second passage is monitored for a further 5 days. If no cytopathic effect is observed in either passage the antigen is considered inactivated.

Result: No growth detected

Visual inspection: Physical properties by Appearance, Colour and Physical State.

Result: Translucent colourless to slightly yellowish liquid

Quality Assurance Signature: Date:

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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.