

PRODUCT DESCRIPTION:

Each aliquot contains 1 ml of polysaccharide antigen suspension obtained from cultured *Cryptococcus neoformans* serotype A. The identification of this organism was confirmed by 26S sequencing. The purity of the culture was monitored by Gram staining and by additional culturing. This control is supplied in 0.2 M NaCl.

INTENDED USE:

This reagent is not a substitute for the mandatory positive control reagents provided with licensed test kits.

This preparation of *Cryptococcus neoformans* polysaccharide antigens is formulated for use as an external run control for enzyme immunoassays, latex agglutination methods, and immunochromatographic assays. Polysaccharide antigens may be included in a test run following the procedure provided by the test kit manufacturer for unknown specimens. Polysaccharide antigens can be used for training, lot-to-lot comparison of reagent test kits and comparison of laboratory performances. It is the responsibility of each laboratory to determine the suitability of polysaccharide antigens reagent for their particular use. They also must establish guidelines for the interpretation of the results.

PRECAUTIONS:

This product is intended for research or product development use only. This product is NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.




RECOMMENDED STORAGE:

- Store the polysaccharide antigens at -65°C or below.
- Polysaccharide antigens are stable for 1 week at 2-8°C after thawing.
- The polysaccharide antigens can be re-frozen after thawing. Repetitive freezing and thawing is not recommended (aliquot material if necessary).

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

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This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

REF	Catalog Number		Temperature Limitation
LOT	Lot Number		Expiration Date
RUO	For Research Use Only		Biological Risk

ZeptoMetrix Corporation
 878 Main Street
 Buffalo, NY 14202
 800-274-5487
www.zeptometrix.com

PROCEDURE:

- Allow polysaccharide antigens to reach room temperature prior to use. Return to proper storage after use.
- Mix content by quick vortexing (2- 3 seconds) prior to use.
- Procedure and interpretation of results provided in package insert of each commercially available test kit must be followed closely when testing the polysaccharide antigens.




PERFORMANCE CHARACTERISTICS:

The polysaccharide antigens were tested using commercially available test systems following the procedures provided by the manufacturer for the testing of unknown specimens. The data contained in this document is intended to be representative of a typical screening of this control and should be used for informational purposes only. Each laboratory should establish its own performance characteristics. See the Certificate of Analysis for more specific information on the testing results.

Test system	Expected Reactivity
(Following the screening procedure detailed in the manufacturer product insert)	
Meridian Cryptococcal Antigen Latex Agglutination System (CALAS®)	POSITIVE
Meridian Premier® Cryptococcal Antigen	POSITIVE
IMMY Latex-Cryptococcus Antigen Detection System	POSITIVE
IMMY Cryptococcus Antigen Lateral Flow Assay	POSITIVE

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