Mycobacterium tuberculosis (TB)

Concentrated and Prediluted Polyclonal Antibody
901-140-072917

BIOCARE MEDICAL

Catalog Number:	**ACI 140 A, C**	**API 140 AA**
Description:	0.1, 1.0 ml, concentrated	6.0 ml, prediluted
Dilution:	1:200	Ready-to-use
Diluent:	Da Vinci Green	N/A

Intended Use:
For In Vitro Diagnostic Use

Summary and Explanation:
This antibody consists of the purified IgG fraction and reacts with Mycobacterium tuberculosis. The emergence of new strains of resistant Mycobacterium tuberculosis has created new interest in clinical diagnosis. Studies have shown immunohistochemical techniques to be superior to conventional special stains. Thus, the demonstration of mycobacterial antigens are not only useful in establishing mycobacterial aetiology, but also can be used as an alternative method to the conventional Ziehl-Neelsen method (1). Studies have shown this antibody is reactive with other Mycobacteria species including: M. avium, M. phlei, and M. parafortuitum. This antibody has been reported not to be reactive with E. coli K12, Salmonella typhimurium, Pseudomonas aeruginosa, Streptococcus (group B), Candida albicans and Neisseria meningitides.

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Principle of Procedure:
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, an enzyme labeled polymer is added to bind to the primary antibody. The detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Rabbit polyclonal
Species Reactivity: Human; others not tested
Clone: N/A
Isotype: N/A
Epitope/Antigen: Mycobacterium tuberculosis
Cellular Localization: N/A
Positive Control: Mycobacterium tuberculosis infected tissue
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative
Storage and Stability:
Store at 2ºC to 8ºC. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations:
Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment Solution (recommended): N/A
Pretreatment Protocol: N/A
Protein Block (**Optional):** Incubate for 5-10 minutes at RT with Biocare's Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Probe: N/A
Polymer: Incubate for 30 minutes at RT with a secondary-conjugated polymer.
Chromogen: Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Biocare's Warp Red.

Counterstain: Counterstain with hematoxylin. Rinse with DI water. Apply Tacha's Bluing Solution for 1 minute. Rinse with DI water.

Technical Note:
This antibody has been standardized with Biocare's MACH 2 detection system. It can also be used on an automated staining system and with other Biocare polymer detection kits. Use TBS buffer for washing steps.

Limitations:
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

Quality Control:
Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

Precautions:
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN_3) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (2)
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (3)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.
5. Do not use reagent after the expiration date printed on the vial.
6. The SDS is available upon request and is located at http://biocare.net.

Troubleshooting:
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

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IVD CE

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References:
1. Radhakrishnan VV, et al. Immunohistochemical demonstration of mycobacterial antigens in intracranial tuberculoma. Indian J Exp Biol. 1991 Jul;29(7):641-4.
2. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."
3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

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