

H. pylori (RM)

Prediluted Rabbit Monoclonal Antibody
901-3191-081017

BIOCARE
M E D I C A L

Catalog Number:	API 3191 AA	OAI 3191 T60
Description:	6.0 ml, prediluted	60 tests, prediluted
Dilution:	Ready-to-use	Ready-to-use
Diluent:	N/A	N/A

Intended Use:

For In Vitro Diagnostic Use

H. pylori (RM) [EP279] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of *H. pylori* protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:

Helicobacter pylori (*H. pylori*) infection represents the major cause of peptic ulcer disease and is a likely contributing factor in the development of gastric neoplastic diseases such as gastric adenocarcinoma and mucosa-associated lymphoid tissue (MALT) lymphoma (1). *H. pylori* are spiral-curved, gram-negative bacteria. The majority of *H. pylori* microorganisms reside in the unstirred layer of the gastric mucus, but some bind to the luminal aspect of gastric foveolar cells, and attach at or near intercellular junctions, or even locate within cells (2-3). However, generally they do not invade the underlying lamina propria (3). Immunohistochemical (IHC) detection of *H. pylori* can specifically distinguish the microorganisms from other types of bacterial infections. Complete staining of the *H. pylori* microorganism has been shown with the rabbit monoclonal. An IHC technique, with heat-induced-antigen retrieval for detection of *H. pylori* in gastric biopsies, is highly reliable, highly sensitive, specific, and can be used on fully automated IHC platforms.

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 monoclonal

Species Reactivity: Human; others not tested

Clone: EP279

Isotype: IgG

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.

Epitope/Antigen: *H. pylori*

Cellular Localization: Spiral shaped bacterium

Positive Tissue Control: Gastric tissue infected with *H. pylori*

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

Storage and Stability:

Store at 2°C to 8°C. 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.

Protocol Recommendations (manual use):

Peroxide Block:

Block for 5 minutes with Biocare's Peroxidized 1.

Pretreatment: Perform heat retrieval using Biocare's Borg Decloaker. Refer to the Borg Decloaker data sheet for specific instructions.

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 deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Protocol Recommendations (ONCORE Automated Slide Staining System):

OAI3191 is intended for use with the ONCORE Automated Slide Staining System. Refer to the ONCORE Automated Slide Staining System User Manual for specific instructions on its use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

Protocol Name: H. pylori Rb

Protocol Template (Description): Rb HRP Template 1

Dewaxing (DS Option): DS2

Antigen Retrieval (AR Option): AR2, low pH; 101°C

Reagent Name, Time, Temp.: H. pylori Rb, 30 min., 37°C

Technical Note:

This antibody has been optimized for use with Biocare's MACH 4 Universal HRP Polymer Detection and ONCORE Rabbit HRP Detection. Use TBS 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

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Limitations Cont'd:

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) (4)
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 into contact with sensitive areas, wash with copious amounts of water. (5)
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.

References:

1. Dunn BE, Cohen H, Blaser MJ. *Helicobacter pylori*. Clin Microbiol Rev. 1997;10:720-41.
2. Boren T, *et al.* Attachment of *Helicobacter pylori* to human gastric epithelium mediated by blood group antigens. Science. 1993; 262:1892-5.
3. Hazell SL, *et al.* *Campylobacter pyloridis* and gastritis: association with inter cellular spaces and adaptation to an environment of mucus as important factors in colonization of the gastric epithelium. J Infect Dis. 1986;153:658-63.
4. 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."
5. 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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