Carcinoembryonic Antigen (CEA {P})

Concentrated and Prediluted Rabbit Polyclonal Antibody
901-009-022818

BIOCARE MEDICAL

Catalog Number:	**CP 009 A, B, C**	**PP 009 AA**	**IP 009 G10**
Description:	0.1, 0.5, 1.0 ml, concentrated	6.0 ml, prediluted	10 ml, prediluted
Dilution:	1:100	Ready-to-use	Ready-to-use
Diluent:	Da Vinci Green	N/A	N/A

Intended Use:
For In Vitro Diagnostic Use
Carcinoembryonic Antigen (CEA {P}) is a rabbit polyclonal antibody that is intended for laboratory use in the qualitative identification of CEA 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:
According to studies, carcinoembryonic antigen reacts with CEA and CEA-like proteins such as NCA (non-specific cross-reacting antigen) and NCA2 and biliary glycoprotein (BGP1). In all tissues, the NCA of neutrophil granulocytes are stained positive. In colon adenocarcinoma, the antibody labels the cytoplasm of the tumor cells strongly. In the normal colon, the luminal part of enterocytes is strongly labelled. In breast carcinoma, a low percentage of glandular epithelial cells are stained. Gland lumina and some epithelial cell membranes in the normal breast tissue show positive staining. In the liver, the biliary canaliculi are positive. In general, CEA will mark adenocarcinoma of the stomach, colon, lung and pancreas; CEA is weakly or occasionally positive (less than 10%) for prostate cancer, bladder cancer and hepatoma. CEA is negative for squamous cell carcinoma of the skin and esophagus, mesothelioma, lymphoma, melanoma and sarcoma.

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. This 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
Total Protein Concentration: ~10 mg/ml. Lot specific Ig concentration is not available.
Epitope/Antigen: CEA
Cellular Localization: Cytoplasmic
Positive Tissue Control: Colon carcinoma
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 (intelliPATH and manual use):
Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment: 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.

Protocol Recommendations (intelliPATH and manual use) Cont'd:
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.

intelliPATH™ Automated Slide Stainer:
IP009 is intended for use on the intelliPATH™ Automated Slide Stainer. Refer to the intelliPATH Automated Slide Stainer manual for specific instructions on its use.

Technical Note:
This antibody has been optimized for use with Biocare's MACH 4 detection system. 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 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) (5)
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. (6)
3. Microbial contamination of reagents may result in an increase in nonspecific staining.

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Precautions Cont'd:
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. Sheahan K, *et al.* Differential reactivities of carcinoembryonic antigen (CEA) and CEA-related monoclonal and polyclonal antibodies in common epithelial malignancies. Am J Clin Pathol. 1990;94:157-64.
2. Nap M, Hoor KAT, Fleuren GJ. Cross-reactivity with normal antigens in commercial anti-CEA sera, used for immunohistology. The need for tissue controls and absorptions. Am J Clin Pathol. 1983;79:25-31.
3. Nap M, *et al.* CEA and NCA in benign and malignant breast tumors. Am J. Clin Pathol. 1984;82:526-34.
4. Taylor & Cote. Immunomicroscopy: A Diagnostic Tool for the Surgical Pathologist.
5. 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."
6. 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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