

CDX2

Concentrated and Prediluted Monoclonal Antibody
901-226-042018

BIOCARE
M E D I C A L

Catalog Number:	CM 226 A, B, C	PM 226 AA, H
Description:	0.1, 0.5, 1.0 ml, concentrated	6.0, 25 ml, prediluted
Dilution:	1:100	Ready-to-use
Diluent:	Van Gogh Yellow	N/A

IP 226 G10	OAI 226 T60	VP 226 G
10 ml, prediluted	60 tests, prediluted	6.0 ml, prediluted
Ready-to-use	Ready-to-use	Ready-to-use
N/A	N/A	N/A

Intended Use:

For In Vitro Diagnostic Use

CDX2 [CDX2-88] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of CDX2 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:

CDX2 is a homeobox gene that encodes an intestine-specific transcription factor. It is expressed in the nuclei of epithelial cells of the intestine, from duodenum to rectum. The CDX2 protein is expressed in primary and metastatic colorectal carcinomas. It has also been identified in intestinal metaplasia of the stomach and in intestinal-type gastric cancer. CDX2 is not expressed in normal gastric mucosa. Studies have shown that the CDX2 marker is superior to CK20.

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. A secondary antibody may be applied to bind the primary antibody, followed by an enzyme labeled polymer; or an enzyme labeled polymer may be applied directly to bind the primary antibody. The detection of the bound primary antibody is evidenced by an enzyme-mediated colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

Clone: CDX2-88

Isotype: IgG1

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

Epitope/Antigen: CDX2

Cellular Localization: Nuclear

Positive Tissue Control: Colon cancer

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. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations (intelliPATH and manual use):

Peroxide Block: Block for 5 minutes with Biocare's Peroxidase 1.

Pretreatment: Perform heat retrieval using Biocare's Reveal Decloaker. Refer to the Reveal Decloaker product 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: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10-20 minutes at RT with a tertiary polymer.

Protocol Recommendations (intelliPATH and manual use)

Cont'd:

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:

IP226 is intended for use on the intelliPATH™ Automated Slide Stainer. Refer to the User Manual for specific instructions for use. When using the intelliPATH, peroxide block with intelliPATH Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.

Protocol Recommendations (ONCORE Automated Slide Staining System):

OAI226 is intended for use with the ONCORE Automated Slide Staining System. Refer to the User Manual for specific instructions for use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

Protocol Name: CDX2

Protocol Template (Description): Ms HRP Template 1

Dewaxing (DS Option): DS Buffer

Antigen Retrieval (AR Option): AR1, high pH; 103°C

Reagent Name, Time, Temp.: CDX2, 30 min., 25°C

Protocol Recommendations (Ventana BenchMark XT / ULTRA Slide Staining Systems):

VP226 is intended for use with the Ventana BenchMark XT / ULTRA Slide Staining Systems. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

- Using **ultraView on XT / ULTRA:**

Template/Detection: ultraView DAB

Pretreatment Protocol: CC1 Standard

Primary Antibody: 32 minutes, No Heat

- Using **OptiView on ULTRA:**

Template/Detection: OptiView DAB IHC

Pretreatment Protocol: CC1 64 minutes

Peroxidase: Pre Primary Peroxidase Inhibitor

Primary Antibody: 32 minutes, No Heat

Technical Note:

This antibody, for intelliPATH and manual use, has been standardized 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

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Limitations Cont'd:

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 (NaN₃) 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) (3)
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. (4)
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. Werling RW, *et al.* CDX2, a highly sensitive and specific marker of adenocarcinomas of intestinal origin: an immunohistochemical survey of 476 primary and metastatic carcinomas. *Am J Surg Pathol.* 2003 Mar;27(3):303-10.
2. Barbareschi M, *et al.* CDX-2 homeobox gene expression is a reliable marker of colorectal adenocarcinoma metastases to the lungs. *Am J Surg Pathol.* 2003 Feb;27 (2):141-9.
3. 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."
4. 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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