PAX8 (M)

Prediluted Monoclonal Antibody
901-438-050923

BIOCARE MEDICAL

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Predilute	API 438 H	25 mL	Ready-to-use	N/A

Intended Use:
For In Vitro Diagnostic Use
PAX8 (M) [BC12] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of PAX8 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:
PAX8 is a member of the paired box (PAX) family of transcription factors. Members of this gene family typically encode proteins which contain a paired box domain, an octapeptide, and a paired-type homeodomain. This family plays critical roles during fetal development and cancer growth. PAX8 is involved in kidney cell differentiation, thyroid development, or thyroid dysgenesis.
PAX8 is expressed in a high percentage of renal cell carcinomas and ovarian cancers. This mouse monoclonal PAX8 antibody [BC12] has been designed to target a restricted epitope and exhibits higher specificity and provides sharper staining than the PAX8 rabbit polyclonal antibody. Unlike the polyclonal PAX8, this mouse monoclonal antibody does not stain B-cells and does not recognize epitopes of pancreatic origin and neuroendocrine cells in stomach and colon; thus, providing superior specificity. The expression of the mouse monoclonal PAX8 target antigens was found in normal kidney, thyroid, and cervix, but was not identified in normal ovary. By Western blot, [BC12] has been shown to recognize PAX8 and not PAX2, PAX5 or PAX6 proteins. PAX8 stains nuclei exclusively and performs well in formalin-fixed paraffin-embedded tissues.
U.S. Patents 8,852,592, 9,417,243, and patents pending.

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, a one- or two-step detection procedure can be employed. The one-step procedure will feature an enzyme-labeled polymer that binds to the primary antibody. A two-step procedure will feature a secondary antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind to the secondary antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.
Source: Mouse monoclonal
Species Reactivity: Human, mouse, rat, cat, and dog
Clone: BC12
Isotype: IgG1
Protein Concentration: Call for lot specific IgG concentration.
Epitope/Antigen: PAX8
Cellular Localization: Nuclear
Positive Tissue Control: Normal kidney, renal cell, or serous ovarian carcinomas
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative.

Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxide Block: Block for 5 minutes with Peroxidazed 1.
Pretreatment: Perform heat retrieval using Diva or Reveal Decloaker. Refer to the Diva or Reveal Decloaker product data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.
Primary Antibody: Incubate for 30-60 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.
Chromogen: Incubate for 5 minutes at RT with Biocare's DAB – OR – Incubate for 5-7 minutes at RT with Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
Technical Notes:
1. Counterstain lightly with hematoxylin as over-staining may mask stained nuclei, especially in clear cell RCC.
2. 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.

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)[8]
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.[9]
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 datasheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

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References:
1. Tacha D, *et al.* PAX8 mouse monoclonal antibody [BC12] recognizes a restricted epitope and is highly sensitive in renal cell and ovarian cancers but does not cross-react with b cells and tumors of pancreatic origin. Appl Immunohistochem Mol Morphol. 2013 Jan; 21(1): 59-63.
2. Tacha D, Zhou D, Cheng L. Expression of PAX8 in normal and neoplastic tissues: a comprehensive immunohistochemical study. Appl Immunohistochem Mol Morphol. 2011 Jul;19(4):293-9.
3. Lotan TL, *et al.* Immunohistochemical panel to identify the primary site of invasive micropapillary carcinoma. Am J Surg Pathol. 2009 Jul; 33(7):1037-41.
4. Viktorová T, *et al.* Expression of PAX2 and PAX8 genes in conventional type of renal carcinoma and their role in the tumor prognosis. Diagn Cytopathol. 2008 Aug; 36(8):568-73.
5. Narlis M, *et al.* Pax2 and Pax8 regulate branching morphogenesis and nephron differentiation in the developing kidney. J Am Soc Nephrol. 2007 Apr; 18(4):1121-9.
6. Moretti L, *et al.* N-terminal PAX8 polyclonal antibody shows cross-reactivity with N-terminal region of PAX5 and is responsible for reports of PAX8 positivity in malignant lymphomas. Mod Pathol. 2012 Feb;25(2):231-6.
7. Lorenzo PI, *et al.* Immunohistochemical assessment of Pax8 expression during pancreatic islet development and in human neuroendocrine tumors. Histochem Cell Biol. 2011 Nov;136(5):595-607.
8. 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."
9. 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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