BIOCARE MEDICAL

ISO 9001&13485 CERTIFIED

PAX8 (M)

Prediluted Monoclonal Antibody

Control Number: 901-438VP-101216

VP Echelon™ Series

Catalog Number: **AVI 438 G**

Description: 6.0 ml, prediluted

Dilution: Ready-to-use

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, 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: Mouse monoclonal

Species Reactivity: Human, mouse, rat, cat and dog

Clone: BC12

Isotype: IgG1

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

Epitope/Antigen: PAX8

Cellular Localization: Nuclear

Positive 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. 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:

Using ***ultra*View™ Detection Kit**

Pretreatment Solution (recommended): CC1

Pretreatment Protocol: Standard

Primary Antibody: Incubate for 32 minutes with No Heat

Technical Note:

Biocare's VP Echelon Series of predilutes have been developed for use with Ventana® Medical Systems, BenchMark® XT Immunohistochemistry Staining System in combination with Ventana® Detection Kits and Ventana® Prep Kit Dispensers.

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 listed are not applicable to other detection systems, as results may vary. 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) (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 data sheet 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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