NKX3.1

Concentrated and Prediluted Polyclonal Antibody
901-422-060223

BIOCARE MEDICAL

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Concentrate	CP 422 A, B	0.1, 0.5 mL	1:100	Renoir Red
Predilute	PP 422 AA	6.0 mL	Ready-to-use	N/A
ONCORE Pro	OPAI 422 T60	60 tests	Ready-to-use	N/A
Q Series– For Leica BOND-III	ALI 422 G7	7.0 mL	Ready-to-use	N/A

Intended Use:
For In Vitro Diagnostic Use
NKX3.1 is a rabbit polyclonal antibody that is intended for laboratory use in the qualitative identification of NKX3.1 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:
NKX3.1 is a protein found in humans and is encoded by the NKX3.1 gene located on chromosome 8. The homeodomain containing transcription factor NKX3A is a putative prostate tumor suppressor that is expressed in a largely prostate-specific and androgen-regulated manner. NKX3.1 protein has been found to be positive in the vast majority of primary prostatic adenocarcinomas. A recent study showed that NKX3.1 staining was highly sensitive and specific for high-grade prostatic adenocarcinomas. The sensitivity for identifying metastatic prostatic adenocarcinomas overall was 98.6% (68/69 cases positive) for NKX3.1, and 94.2% (65/69 cores positive) for PSA. The specificity of NKX3.1 was 99.7% (1/349) in various cancers. NKX3.1 stains nuclei in both normal and prostate cancer, thus providing a robust stain that is easy-to-interpret, similar to other transcription factors such as TTF-1 or CDX2.
In the appropriate clinical setting, the addition of IHC staining for NKX3.1, along with other prostate-restricted markers, may prove to be a valuable adjunct to definitively determine prostatic origin in poorly differentiated metastatic carcinomas. NKX3.1 used in combination with ERG monoclonal antibody [9FY], may represent one of the most sensitive and specific markers for identifying tumors of prostatic origin.

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-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Rabbit polyclonal
Species Reactivity: Human; others not tested
Clone: N/A
Isotype: N/A
Protein Concentration: Lot specific Ig concentration is not available.
Epitope/Antigen: Human NKX3.1 protein
Cellular Localization: Nuclear
Positive Tissue Control: Normal prostate or prostate cancer
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 Reveal or Diva Decloaker. Refer to the Reveal or Diva 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 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 Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
Technical Note:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):
OPAI422 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: NKX3.1 Rb
Protocol Template (Description): Rb HRP Template 1
Dewaxing (DS Buffer Option): DS Buffer
Antigen Retrieval (AR Option): AR1, high pH; 103°C
Block Option: Buffer
Reagent Name, Time, Temp.: NKX3.1 Rb, 30 min., 37°C

Protocol Recommendations (Q Series – For Leica BOND-III):
ALI422 is intended for use with the Leica BOND-III. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:
Protocol Name: IHC Protocol F
Detection: Bond Polymer Refine
HIER: 30 min with ER1
Peroxide Block: 5 min
Marker (Primary Antibody): 15 min
Post Primary: 8 min
Polymer: 8 min
Mixed DAB Refine: 10 min
Hematoxylin: 5 min

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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) (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. Bowen C, Gelmann EP. NKX3.1 activates cellular response to DNA damage. Cancer Res. 2010 Apr 15; 70(8):3089-97.
2. Gurel B, *et al.* NKX3.1 as a marker of prostatic origin in metastatic tumors. Am J Surg Pathol. 2010 Aug; 34(8):1097-105.
3. Chuang AY, *et al.* Immunohistochemical differentiation of high-grade prostate carcinoma from urothelial carcinoma. Am J Surg Pathol. 2007 Aug; 31(8):1246-55.
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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