

Napsin A (RM)

Concentrated and Prediluted Rabbit Monoclonal Antibody
901-3043-050819

BIOCARE
M E D I C A L

Catalog Number:	ACI 3043 A, C	API 3043 AA	VLTR 3043 G20
Description:	0.1, 1.0, mL conc.	6.0 mL, RTU	20 mL, RTU
Dilution:	1:100	Ready-to-use	Ready-to-use
Diluent:	Renoir Red	N/A	N/A

Intended Use:

For In Vitro Diagnostic Use

Napsin A [BC15] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of Napsin A 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:

Napsin A is a pepsin-like aspartic proteinase. It is expressed in type II pneumocytes and in most lung adenocarcinomas and some renal cell carcinomas. Studies have shown that Napsin A is a more sensitive and specific marker than TTF-1 and is extremely specific for lung adenocarcinomas (1-6). Most studies show Napsin A is highly specific for lung adenocarcinoma versus lung SqCC (1-4).

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 monoclonal

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

Clone: BC15

Isotype: IgG

Protein Concentration: Call for lot specific Ig concentration.

Epitope/Antigen: Napsin A

Cellular Localization: Cytoplasmic (granular)

Positive Tissue Control: Lung adenocarcinoma

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. 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 2°C to 8°C.

Protocol Recommendations (VALENT® Automated Slide Staining Platform):

VLTR3043 is intended for use with the VALENT. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Manager should be programmed as follows:

Deparaffinization: Deparaffinize for 8 minutes with Val DePar.

Pretreatment: Perform heat retrieval at 98°C for 60 minutes using Val AR-Hi pH, 5X (use at 1X).

Peroxidase Block: Block for 5 minutes with Val Peroxidase Block.

Protein Block (Optional): Incubate for 10-20 minutes with Val Background Block.

Primary Antibody: Incubate for 45 minutes.

Secondary: N/A

Linker: Incubate for 10 minutes with Val Universal Linker.

Protocol Recommendations (VALENT Automated Slide Staining Platform) Cont'd:

Polymer: Incubate for 20 minutes with Val Universal Polymer.

Chromogen: Incubate for 5 minutes with Val DAB.

Counterstain: Counterstain for 5 minutes with Val Hematoxylin.

Protocol Recommendations (intelliPATH FLX® and manual use):

Peroxide Block: Block for 5 minutes with Peroxidized 1.

Pretreatment: Perform heat retrieval using Diva Decloaker. Refer to the Diva Decloaker 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.

Performance Characteristics:

Sensitivity, specificity and cross-reactivity testing of Napsin A [BC15] was performed by staining with MACH 4 Universal HRP-Polymer Detection. See Tables 1 and 2 for expected results.

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 (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) (6)

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

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Precautions Cont'd:

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. (7)

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. Mukhopadhyay S, Katzenstein AL. Subclassification of non-small cell lung carcinomas lacking morphologic differentiation on biopsy specimens: Utility of an immunohistochemical panel containing TTF-1, napsin A, p63, and CK5/6. 2011 Jan; 35(1):15-25.

2. Bishop JA, Sharma R, Illei PB. Napsin A and thyroid transcription factor-1 expression in carcinomas of the lung, breast, pancreas, colon, kidney, thyroid, and malignant mesothelioma. Hum Pathol. 2010 Jan; 41(1):20-5.

3. Jagirdar J. Application of immunohistochemistry to the diagnosis of primary and metastatic carcinoma to the lung. Arch Pathol Lab Med. 2008 Mar; 132(3):384-96.

4. Dejmek A, *et al.* Napsin A (TA02) is a useful alternative to thyroid transcription factor-1 (TTF-1) for the identification of pulmonary adenocarcinoma cells in pleural effusions. Diagn Cytopathol. 2007 Aug; 35(8):493-7.

5. Suzuki A, *et al.* Napsin A is useful to distinguish primary lung adenocarcinoma from adenocarcinomas of other organs. Pathol Res Pract. 2005; 201(8-9):579-86.

6. 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."

7. 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.

Table 1: Sensitivity and specificity of rabbit monoclonal antibody Napsin A (RM) [BC15] was determined by testing formalin-fixed, paraffin-embedded neoplastic tissues.

Cancer Type	Positive	Negative	% (+)
Lung adenocarcinoma	55	11	83.3%
Lung SqCC	0	21	0.0%
Prostate cancer	0	15	0.0%
Bladder cancer	0	11	0.0%
Renal cancer	0	11	0.0%
Colon cancer	0	36	0.0%
Breast cancer	0	16	0.0%
Ovarian cancer	0	1	0.0%
Glioblastoma	0	1	0.0%
GIST	0	1	0.0%
Melanoma	0	1	0.0%
Rhabdomyosarcoma	0	1	0.0%
Melanoma	0	1	0.0%
Leiomyosarcoma	0	1	0.0%
Seminoma	0	1	0.0%

Table 2: Cross-reactivity of rabbit monoclonal antibody Napsin A (RM) [BC15] was determined by testing formalin-fixed, paraffin-embedded normal tissues.

Normal Organ Tissue	Positive	Negative	% (+)
Normal kidney	11	0	100.0%
Liver	0	1	0.0%
Cerebellum	0	1	0.0%
Pituitary	0	1	0.0%
Adrenal gland	0	1	0.0%
Thymus	0	1	0.0%
Thyroid	0	1	0.0%
Tonsil	0	1	0.0%
Ovary	0	1	0.0%
Uterus	0	1	0.0%
Smooth muscle	0	1	0.0%
Fallopian tube	0	1	0.0%
Placenta	0	1	0.0%
Bladder	0	1	0.0%
Urethra	0	1	0.0%
Breast	0	1	0.0%
Prostate	0	1	0.0%
Testis	0	1	0.0%
Heart	0	1	0.0%