

Cytokeratin HMW [34βE12]

Concentrated and Prediluted Monoclonal Antibody
901-127-082622

BIOCARE
M E D I C A L

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
Q Series— For Leica BOND-III	ALI 127 G7	7.0 mL	Ready-to-use	N/A

Intended Use: For In Vitro Diagnostic Use

Cytokeratin HMW [34βE12] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of high molecular weight cytokeratin proteins (CK 1, 5, 10, 14) 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:

34βE12 recognizes cytokeratins (CK) 1, 5, 10 and 14. This antibody is reactive with squamous and adeno-squamous carcinomas; adenocarcinomas are negative (2,4). Studies have shown in normal epithelia, 34βE12 stains stratified epithelia, myoepithelial cells and basal cells in the prostate gland and bronchi.

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: Mouse monoclonal

Species Reactivity: Human

Clone: 34βE12

Isotype: IgG1/kappa

Protein Concentration: Call for lot specific Ig concentration.

Epitope/Antigen: HMW CK [34βE12]

Cellular Localization: Cytoplasmic

Positive Tissue Control: Skin, prostate or squamous cell carcinoma

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 (Q Series – For Leica BOND-III):

ALI127 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: 20 min with ER2

Peroxide Block: 5 min

Marker (Primary Antibody): 15 min

Post Primary: 8 min

Polymer: 8 min

Mixed DAB Refine: 10 min

Hematoxylin: 5 min

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

Limitations Cont'd:

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) (5)

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. (6)

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. Moifar F, *et al.* Use of keratin 35betaE12 as an adjunct in the diagnosis of mammary intraepithelial neoplasia-ductal type--benign and malignant intraductal proliferations. *Am J Surg Pathol.* 1999 Sep;23(9):1048-58.

2. Varma M, *et al.* Effect of formalin fixation and epitope retrieval techniques on antibody 34betaE12 immunostaining of prostatic tissues. *Mod Pathol.* 1999 May;12(5):472-8.

3. Iczkowski KA, *et al.* Steam heat with an EDTA buffer and protease digestion optimizes immunohistochemical expression of basal cell-specific antikeratin 34betaE12 to discriminate cancer in prostatic epithelium. *Mod Pathol.* 1999 Jan;12(1):1-4.

4. Morice WG, Ferreiro JA. Distinction of basaloid squamous cell carcinoma from adenoid cystic and small cell undifferentiated carcinoma by immunohistochemistry. *Hum Pathol.* 1998 Jun;29(6):609-12.

5. 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."

6. 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.

Q Series antibodies are developed solely by Biocare Medical LLC and do not imply approval or endorsement of Biocare antibodies by Leica Biosystems. Biocare and Leica Biosystems are not affiliated, associated or related in any way. Leica, Leica Biosystems, BOND-MAX and BOND-III are trademarks of Leica Biosystems.



60 Berry Drive
Pacheco, CA 94553
USA



TP v1 (10/26/2021)

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080