

| Available Product Formats | | | | |
|------------------------------|----------------|-------------|--------------|------------|
| Format | Catalog Number | Description | Dilution | Diluent |
| Concentrate | CME 415 AK, CK | 0.1, 1.0 mL | 1:100 | Renoir Red |
| Predilute | PME 415 AA | 6.0 mL | Ready-to-use | N/A |
| UltraLine – For BenchMark | AVI 415 G | 6.0 mL | Ready-to-use | N/A |
| Q Series- For Leica BOND-III | ALI 415 G7 | 7.0 mL | Ready-to-use | N/A |

Intended Use:

For In Vitro Diagnostic Use

c-Myc [EP121] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of c-Myc 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:

The oncogene-encoded protein c-Myc is a transcription factor localized to the nucleus of the cell. c-Myc is postulated to play a role in activating the transcription of growth related genes, thereby influencing cell proliferation, differentiation, apoptosis, and cell cycle progression (1-4). Amplification of the c-Myc gene has been found in several types of human tumors. Studies have shown that c-Mvc is essential for vasculogenesis and angiogenesis in neoplastic disease (2). c-Myc oncogene activity may also be necessary for the translocation(s) seen in human breast tumors identified to have a poor-prognosis signature and metastasis to distant sites (1,3). Over-expression of the c-Myc oncogene has been implicated in the development and progression of human prostate carcinoma (2,4).

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, others not tested Clone: EP121 (previously known as Y69)

Isotype: IqG

Protein Concentration: Call for lot specific Iq concentration. Epitope/Antigen: Synthetic peptide corresponding to residues in Nterminus of human c-Mvc

Cellular Localization: Nuclear

Positive Tissue Control: Some prostate or breast cancer

Known Applications:

Immunohistochemistry (formalin-fixed paraffin-embedded tissues) Supplied As: Buffer with protein carrier and preservative

Renoir Red Diluent (PD904)

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 (intelliPATH FLX® and manual use):

Peroxide Block: Block for 5 minutes with Peroxidazed 1. Pretreatment: Perform heat retrieval using Diva or Borg Decloaker.

Refer to the Diva or Borg 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: 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 (Ventana BenchMark ULTRA):

AVI415 is intended for use with the BenchMark ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

Template/Detection: OptiView DAB IHC Pretreatment Protocol: CC1 48 minutes Peroxidase: Pre Primary Peroxidase Inhibitor Primary Antibody: 32 minutes, 36°C Amplification Kit: 4 minutes, 4 minutes

Protocol Recommendations (Q Series - For Leica BOND-III):

ALI15 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: 40 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 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



c-Myc

Concentrated and Prediluted Rabbit Monoclonal Antibody 901-415-052323



Limitations Cont'd:

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 in 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. Wolfer A, *et al.* MYC regulation of a "poor-prognosis" metastatic cancer cell state. Proc Natl Acad Sci U S A. 2010 Feb 23; 107(8):3698-703.

2. Gurel B, *et al.* Nuclear MYC protein overexpression is an early alteration in human prostate carcinogenesis. Mod Pathol. 2008 Sep; 21(9):1156-67.

3. Park K, *et al.* c-myc amplification is associated with HER2 amplification and closely linked with cell proliferation in tissue microarray of nonselected breast cancers. Hum Pathol. 2005 Jun; 36(6):634-9.

4. Yang G, *et al.* Combined c-Myc and caveolin-1 expression in human prostate carcinoma predicts prostate carcinoma progression. Cancer. 2005 Mar 15; 103(6):1186-94.

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.

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