# p40 (M), 3X (Prostate)

Prediluted Monoclonal Antibody

Control Number: 901-3079-092017

**Catalog Number:** **API 3079 G3**

**Description:** 3.0 ml, prediluted

**Dilution:** Ready-to-use

**Diluent:** N/A

**Intended Use:**

For In Vitro Diagnostic Use

p40 (M), 3X (Prostate) [BC28] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of p40 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human prostate 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 mouse monoclonal antibody p40 [BC28] recognizes an epitope unique to the p40 protein and may have applications in cases where p63 has traditionally been used. To date, p63 [4A4] has been a frequently used marker of basal epithelium in normal prostate, but expression is not usually observed in prostatic adenocarcinoma (1). Studies have shown p40 staining of normal prostate glands and prostatic intraepithelial neoplasia (PIN) was equivalent to p63, with no staining of p40 observed in prostate cancer (2).

p63 [4A4] recognizes both the p63 and p40 proteins (3). p40 (M) [BC28] recognizes an epitope unique to p40, which may result in sensitivity equal to p63, with improved specificity and staining quality. In contrast to the rabbit polyclonal p40 antibody, p40 (M) [BC28] does not stain macrophages. U.S. Patent 9,428,576 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; others not tested

**Clone:** BC28

**Isotype:** IgG1

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

**Epitope/Antigen:** amino acids 5-17 of p40

**Cellular Localization:** Nuclear

**Positive Tissue Control:** Normal prostate or prostate cancer containing normal glands

**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. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

**Protocol Recommendations:**

**Peroxide Block:**

Block for 5 minutes with Biocare's Peroxidazed 1.

**Pretreatment:** Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.

**Protocol Recommendations:**

**Protein Block (Optional):** Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

**Primary Antibody:** Incubate for 10 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.

**Counterstain:**

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

**Technical Note:**

1. This antibody has been standardized with Biocare's MACH 2 DS 2 detection system.
2. Use TBS buffer for washing steps.
3. If this reagent is used in combination with other primary antibodies, the antibody incubation time may need to be extended up to 30 minutes, depending upon the particular protocol of the individual investigator.

**Performance Characteristics:**

Nuclear staining of p40 (M) [BC28] was observed in 97% (65/67) of cases of lung squamous cell carcinoma, with no staining observed in lung adenocarcinoma cases (n=71) (Table 1). Staining of p40 (M) was also observed in 85.5% (41/48) of cases of urothelial carcinoma and 78% (46/59) of cases of head and neck squamous cell carcinomas. In breast cancers, only myoepithelial cells in ductal carcinoma *in situ* (DCIS) stained with p40 (M). No cases of prostate cancer were found to be positive with p40 (M).

p40 (M) [BC28] nuclear staining was observed in the expected normal tissues: basal cells in prostate, myoepithelial cells in breast, urothelial cells in bladder (but not umbrella cells), stratified epithelial cells in skin, tonsil, esophagus and cervical mucosa, cytotrophoblasts in placenta, and extremely low staining in thymus and spleen (Table 2).

**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. 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

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**Precautions Cont'd:**

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.

**References:**

1. Signoretti S, *et al.* p63 is a prostate basal cell marker and is required for prostate development. Am J Pathol. 2000 Dec; 157(6):1769-75.

2. Sailer V, *et al.* Comparison of p40 and p63 expression in prostate tissues - which one is the superior diagnostic marker for basal cells? Histopathology. 2013 Jul; 63(1):50-6.

3. Bishop JA, *et al.* p40 is superior to p63 for the diagnosis of pulmonary squamous cell carcinoma. Mod Pathol. 2012 Mar; 25(3):405-15.

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.

**Table 1:** Sensitivity of mouse monoclonal antibody p40 (M) [BC28] was determined by testing formalin-fixed, paraffin-embedded neoplastic tissues.

| Pathology | Number of Specimens | Number of Positive Specimens | % Positive |
|---|---|---|---|
| Lung squamous cell carcinoma | 67 | 65 | 97.0% |
| Lung adenocarcinoma | 71 | 0 | 0% |
| Urothelial carcinoma | 48 | 41 | 85.5% |
| Head and neck squamous cell carcinoma | 59 | 46 | 78.0% |
| Breast cancer | 65 | 18 | 27.6% |
| Prostate cancer | 12 | 0 | 0% |

**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.

**Table 2:** Specificity of mouse monoclonal antibody p40 (M) [BC28] was determined by testing formalin-fixed, paraffin-embedded normal tissues.

| Tissue | # positive / total tissues | Tissue | #positive / total tissues |
|---|---|---|---|
| Adrenal gland | 0/3 | Ovary | 0/3 |
| Bladder, urinary | 2/3 | Pancreas | 0/3 |
| Bone marrow | 0/1 | Parathyroid | 0/3 |
| Eye | 0/1 | Pituitary gland | 0/2 |
| Breast | 3/3 | Placenta | 1/3 |
| Brain, cerebellum | 0/3 | Prostate | 3/3 |
| Brain, cerebral cortex | 0/3 | Skin | 1/1 |
| Fallopian tube | 0/3 | Spinal Cord | 0/2 |
| Esophagus | 3/3 | Spleen | 0/2 |
| Stomach | 0/3 | Skeletal Muscle | 0/3 |
| Intestine, small intestine | 0/3 | Testis | 0/3 |
| Intestine, colon | 0/3 | Thymus | 0/3 |
| Intestine, rectum | 0/3 | Thyroid | 0/3 |
| Heart | 0/3 | Inflammatory Tonsillitis* | 3/3 |
| Kidney | 0/6 | Ureter | 3/3 |
| Liver | 0/3 | Uterus cervix | 3/3 |
| Lung | 0/3 | Uterus endometrium | 0/3 |

*B and T cells are negative. Only normal squamous epithelium is positive.

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