# p40 (P)

Concentrated and Prediluted Polyclonal Antibody
901-3030-040919

BIOCARE MEDICAL

| Catalog Number: | ACI 3030 A, B | API 3030 AA | VLTR 3030 G20 |
|---|---|---|---|
| Description: | 0.1, 0.5 mL, conc. | 6.0 mL, RTU | 20 mL, RTU |
| Dilution: | 1:100 | Ready-to-use | Ready-to-use |
| Diluent: | Renaissance Background Reducing | N/A | N/A |

**Intended Use:**
For In Vitro Diagnostic Use
p40 (P) is a rabbit polyclonal antibody that is intended for laboratory use in the qualitative identification of p40 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:**
p40 recognizes the shortest variant of human p53, and may be a valuable marker in cases where p63 has traditionally been used. At present, p63 is the most frequently used marker for lung squamous cell carcinoma (SqCC). Studies have shown that p63 is extremely sensitive for SqCC; however, it suffers from specificity limitations due to its reactivity in a subset of lung adenocarcinomas. Diagnosing non-small cell lung cancer (NSCLC) by morphology in small samples (e.g. biopsy, cellblock, FNA) can be difficult. Given that conserving tissue for molecular testing is a priority, a minimalist immunohistochemistry (IHC)-based diagnostic approach is warranted.
In a study, p40 staining was equivalent to p63 in sensitivity for SqCC, but exhibited markedly superior specificity vs. p63, which eliminated a potential pitfall of misinterpreting a p63-positive adenocarcinoma as squamous cell carcinoma (1). This report strongly supports the routine use of p40 as an alternative for p63 for the diagnosis of pulmonary squamous cell carcinoma. p40 may prove to be an important antibody in the differential diagnosis of lung adenocarcinoma vs. lung SqCC.

**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
**Immunogen:** a synthetic peptide corresponding to amino acids 5-17 of human p40
**Clone:** N/A
**Isotype:** IgG
**Protein Concentration:** Lot specific Ig concentration is not available.
**Epitope/Antigen:** amino acids 5-17 of p40 (ΔNp63)
**Cellular Localization:** Nuclear
**Positive Tissue Control:** Lung SqCC

**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 (VALENT® Automated Slide Staining Platform):**
VLTR3030 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 – OR – Val AR-Lo 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 30 minutes.
**Secondary:** N/A
**Linker:** Incubate for 10 minutes with Val Universal Linker.
**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 Peroxidazed 1.
**Pretreatment**: Perform heat retrieval using Diva Decloaker. Refer to the Diva Decloaker product data sheet for specific instructions.
**Protein Block**: Incubate for 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:**
1. This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.
2. Lot-to-lot staining variability may occur with polyclonal antibodies.
3. Light cytoplasmic staining of smooth muscle and blood vessels may be observed, which should be considered negative for p40 expression.

**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

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

Rev: 062117

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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

# p40 (P)

Concentrated and Prediluted Polyclonal Antibody
901-3030-040919

BIOCARE MEDICAL

**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) (3)
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. (4)
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. Bishop JA, *et al*. p40 (ΔNp63) is superior to p63 for the diagnosis of pulmonary squamous carcinoma. Mod Pathol. 2012 Mar; 25(3):405-15.
2. Pelosi G, *et al*. ΔNp63 (p40) and thyroid transcription factor-1 immunoreactivity on small biopsies or cell blocks for typing non-small cell lung cancers: a novel two-hit, sparing-material approach. J Thorac Oncol. 2012 Feb; 7(2):281-90.
3. 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."
4. 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.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD CE

Rev: 062117

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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