Intended Use:
For In Vitro Diagnostic Use
p53 [EP9] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of p53 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:
p53 acts both as a tumor-suppressor and transcription factor. Activation of DNA damage or other stress signals triggers cell-cycle arrest, apoptosis and DNA repair. The nuclear p53 gene is located on chromosome 17p, a frequent site of allele loss in many tumors (60%) including breast, colon and lung. Studies have shown this high affinity p53 rabbit monoclonal is very specific and is superior to other p53 mouse monoclonal antibodies. This antibody recognizes both wild-type and mutant p53.

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: EP9 (previously known as Y5)
Isotype: IgG
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: p53
Cellular Localization: Nuclear
Positive Tissue Control: Breast and colon carcinomas
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative, Van Gogh Yellow (PD902)
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 (ONCORE™ Pro Automated Slide Staining System):

OPAI298 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

**Protocol Name:** p53 Rb  
**Protocol Template (Description):** Rb HRP Template 1  
**Dewaxing (DS Buffer Option):** DS2-50  
**Antigen Retrieval (AR Option):** AR2, low pH; 101°C  
**Block Option:** Buffer  
**Reagent Name, Time, Temp.:** p53 Rb, 30 min., 25°C  

**Protocol Recommendations (Ventana BenchMark ULTRA):**

AVI298 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 32 minutes  
**Peroxidase:** Pre Primary Peroxidase Inhibitor  
**Primary Antibody:** 32 minutes, 36°C

**Limitations:**
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixed, 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 titer listed are not applicable to other detection systems, as results may vary. The data sheet recommends and protocols are based on the exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

**Quality Control:**

**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) (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:**

Produced using Abcam’s RabMab® technology. RabMab® technology is covered by the following U.S. Patents, No. 5,675,063 and/or 7,429,487.

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