

## p16 INK4a [BC42]

Format	Catalog no.	Pack size	Dilution
Concentrated	GB-c 3231 A,C	0.1, 1.0 mL	1:100
Prediluted	GB-p 3231 AA,H	6.0, 25 mL	Ready to use

### PRODUCT DESCRIPTION -

p16 INK4a is a tumor suppressor protein implicated in the development of many cancers. It is a selective inhibitor of CDK4/CDK6. Recent investigations of the p16INK4a gene identified homozygous deletions, nonsense mutations, missense mutations, or frameshift mutations in several human malignancies. The prevalence of p16 INK4a anomalies is greater in tumor-derived cell lines compared to unselected primary tumors; yet, notable subgroups of clinical cases exhibiting aberrant p16 INK4a genes have been documented in melanomas, gliomas, esophageal, pancreatic, lung, and urinary bladder carcinomas. P16 immunoreactivity in paraffin-embedded tissues has been demonstrated as an independent predictor in minimally invasive urothelial bladder cancer, a prognostic factor in non-small cell lung carcinoma, and an indicator of a favorable response to chemoradiotherapy in Stage IV head and neck squamous cell carcinoma.

### INTENDED USE -

For In Vitro Diagnostic Use p16 INK4a [BC42] is a mouse monoclonal antibody designed for laboratory application in the qualitative detection of p16 INK4a protein via immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical assessment of any staining or its absence must be supplemented by morphological analyses with appropriate controls and should be considered in conjunction with the patient's clinical history and other diagnostic evaluations by a certified pathologist.

### SUMMARY AND EXPLANATION -

p16 INK4a is a tumor suppressor protein implicated in the development of many cancers. It is a selective inhibitor of CDK4/CDK6. Recent investigations of the p16INK4a gene have identified homozygous deletions, nonsense mutations, missense mutations, or frameshift mutations in several human malignancies. The prevalence of p16 INK4a abnormalities is greater in tumor-derived cell lines compared to unselected primary tumors; however, notable subsets of clinical cases exhibiting aberrant p16 INK4a genes have been documented in melanomas,

gliomas, oesophageal, pancreatic, lung, and urinary bladder carcinomas. Immunoreactivity in paraffin-embedded tissues has been demonstrated as an independent predictor in minimally invasive urothelial bladder cancer, a prognostic factor in non-small cell lung carcinoma, and an indicator of a favourable response to chemoradiotherapy in Stage IV head and neck squamous cell carcinoma.

PRINCIPLE OF PROCEDURE -

The principle of the procedure is a multi-step immunohistochemical method for antigen detection in tissues and cells. The first step attaches the primary antibody to its designated epitope.

Following the tagging of the antigen with a primary antibody, a one-, two-, or three-step detection protocol may be utilized. The one-step approach will utilize an enzyme-conjugated polymer that attaches to the main antibody. A two-step approach will involve the addition of a secondary antibody to bind to the primary antibody. A polymer conjugated with an enzyme is subsequently introduced to attach to the secondary antibody. The three-step detection protocol will include the addition of a secondary antibody to bind to the main antibody, succeeded by a linker antibody step to enhance binding efficacy. An enzyme-conjugated polymer is subsequently introduced to attach to the linker antibody. The detection of bound antibodies is demonstrated using a colorimetric response.

SOURCE - Monoclonal mouse

SPECIES REACTIVITY - Human; others not evaluated

CLONE - BC42

ISOTYPE - IgG1/kappa

PROTEIN CONCENTRATION - Request for lot-specific immunoglobulin concentration.

EPITOPE/ANTIGEN - p16 INK4a

CELLULAR LOCALIZATION - Nuclear and Cytoplasmic POSITIVE TISSUE CONTROL -

Normal tonsils, cervical carcinoma, head and neck carcinoma, and colorectal carcinoma

KNOWN APPLICATIONS - Immunohistochemistry

30-40 min. At RT. Staining of formalin-fixed tissues requires heating tissue sections in between pH 7.4 - 9.0 for 45 min at 95°C followed by cooling at room temperature for 20 minutes.

SUPPLIED AS - Buffer containing a 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.

Materials required but not provided -

- 1) Positive tissue control - Normal tonsils, cervical carcinoma, head and neck carcinoma, and colorectal carcinoma
- 2) Negative control tissue (internal or external)
- 3) Microscope slides and coverslips
- 4) Staining jars or baths
- 5) Timer
- 6) Xylene or xylene substitute
- 7) Ethanol or reagent alcohol
- 8) Deionized or distilled water
- 9) Heating equipment or enzyme for tissue pretreatment step
- 10) Detection system
- 11) Chromogen
- 12) Wash buffer
- 13) Hematoxylin
- 14) Antibody diluents
- 15) Peroxide block
- 16) Light microscope
- 17) Mounting medium

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 Genebio products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.