

## p16-INK4 (MX007)

### Mouse anti-human p16<sup>INK4A</sup> Monoclonal Antibody (Clone MX007)

#### References and presentations<sup>1</sup>

- **ready-to-use (manual or LabVision AutoStainer)**  
MAD-000690QD-3  
MAD-000690QD-7  
MAD-000690QD-12
- **Ready-to-use (MD-Stainer)<sup>2</sup>**  
MAD-000690QD-3/V  
MAD-000690QD/V
- **concentrated**  
MAD-000690Q - 1:100 recommended dilution

**Composition:** anti-human p16<sup>INK4A</sup> mouse monoclonal antibody purified from serum and prepared in 10mM PBS, pH 7.4, with 0.2% BSA and 0.09% sodium azide

**Intended use** : Immunohistochemistry (IHC) on paraffin embedded tissues. Not tested on frozen tissues or Western-Blotting

**Clone:** MX007

**Ig isotype:** mouse IgG kappa

**Species reactivity:** In vitro diagnostics in humans. Not tested in other species

**Description and applications:** As one of the cyclin-dependent kinase inhibitors that inhibit cyclin-dependent kinases 4 and 6, p16 INK4A is encoded by tumor suppressor gene CDKN2A. The tumor suppressor p16 INK4A plays an important role in cell cycle regulation. Increased expression of the p16 gene, which is seen as organisms ages, reduces the proliferation of stem cells. This reduction in the division and production of stem cells protects against cancer while increasing the risks associated with cellular senescence. Mutations in the p16 gene associated with loss or over expression of the protein are associated with increased risk of a wide range of cancers and cancer precursor lesions.

The immunohistochemical identification of p16 is particularly relevant in uterine cervical lesions.

Development of dysplasia is closely related to human papilloma virus (HPV) infection.

Although the frequency of p16INK4a abnormalities is higher in tumor-derived cell lines than in unselected primary tumors, significant subsets of clinical cases with aberrant p16INK4a gene have been reported among melanomas, gliomas, esophageal, pancreatic, lung, and urinary bladder carcinomas, and some types of leukemia.

**IHC positive control:** Tonsil, cervical dysplasia

**Visualization:** Cell nuclei and cytoplasm

#### IHC recommended procedure:

- 4µm thick section should be taken on charged slides; dry overnight at 60°C
- Deparaffinise, rehydrate and HIER (heat induced epitope retrieval) – boil tissue in the Pt Module using Vitro S.A EDTA buffer pH8<sup>3</sup> for 20 min at 95°C. Upon completion rinse with 3-5 changes of distilled or deionised water followed by cooling at RT for 20 min
- Endogenous peroxidase block - Blocking for 10 minutes at room temperature using peroxidase solution (ref. MAD-021540Q-125)
- Primary antibody: incubate for 10 minutes [The antibody dilution (when concentrated) and protocol may vary depending on the specimen preparation and specific application. Optimal conditions should be determined by the individual laboratory]
- For detection use Master Polymer Plus Detection System (HRP) (DAB included; ref. MAD-000237QK)
- Counterstaining with haematoxylin and final mounting of the slide

**Storage and stability:**  Stored at 2-8°C. Do not freeze.  Once the packaging has been opened it can be stored until the expiration date of the reagent indicated on the label. If the reagent has been stored under other conditions to those indicated in this document, the user must first check its correct performance taking into account the product warranty is no longer valid.

<sup>1</sup> These references are for presentation in vials of Low Density Polyethylene (LDPE) dropper. In case the products are used in automated stainers, a special reference is assigned as follows:

- / L: Cylindrical screw-cap vials (QD-3 / L, QD-7 / L, QD-12 / L).

- / N: Polygonal screw-cap vials (QD-3 / N, QD-7 / N, QD-12 / N).

For different presentations (references / volumes) please contact the supplier.

<sup>2</sup> For Technical specifications for MD-Stainer, please contact your distributor.

<sup>3</sup> Ref: MAD-004072R/D



**Warnings and precautions:**

1. Avoid contact of reagents with eyes and mucous membranes. If reagents come into contact with sensitive areas, wash with copious amounts of water.
2. This product is harmful if swallowed.
3. Consult local or state authorities with regard to recommended method of disposal.
4. Avoid microbial contamination of reagents.

**Safety Recommendations:**

This product is intended for laboratory professional use only. The product is NOT intended to be used as a drug or for domestic purposes. The current version of the Safety Data Sheet for this product can be downloaded by searching the reference number at [www.vitro.bio](http://www.vitro.bio) or can be requested at [regulatory@vitro.bio](mailto:regulatory@vitro.bio).

**Bibliography:**

1. Sano T, Oyama T, Kashiwabara K, Fukuda T, Nakajima T. Expression status of p16 protein is associated with human papillomavirus oncogenic potential in cervical and genital lesions. *Am J Pathol.* 1998 Dec;153(6):1741-8.
2. Mulvany NJ, Allen DG, Wilson SM. Diagnostic utility of p16INK4a: a reappraisal of its use in cervical biopsies. *Pathology.* 2008 Jun;40(4):335-443
3. Carozzi F, Gillio-Tos A, Confortini M, Del Mistro A, Sani C, De Marco L, Girlando S, Rosso S, Naldoni C, Dalla Palma P, Zorzi M, Giorgi-Rossi P, Segnan N, Cuzick J, Ronco G; NTCC working group. Risk of high-grade cervical intraepithelial neoplasia during follow-up in HPV-positive women according to baseline p16-INK4A results: a prospective analysis of a nested substudy of the NTCC randomised controlled trial. *Lancet Oncol.* 2013 Feb;14(2):168-76.
4. Nishio S, Fujii T, Nishio H, Kameyama K, Saito M, Iwata T, Kubushiro K, Aoki D. p16(INK4a) immunohistochemistry is a promising biomarker to predict the outcome of low grade cervical intraepithelial neoplasia: comparison study with HPV genotyping. *J Gynecol Oncol.* 2013 Jul;24(3):215-21

**LABEL AND BOX SYMBOLS**

Explanation of the symbols of the product label and box:

	Expiration date
	Temperature limit
	Manufacturer
	Sufficient content for <n> assays
	Catalog number
	Lot code
	Refer to the instructions of use
	Medical product for <i>in vitro</i> diagnosis.
	Material safety data sheet

