

Tissue-Tek Genie®

anti-p16 Mouse Monoclonal Antibody [MX007]

Instructions for use

Intended use

For *in vitro* diagnostic use.

Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007] is designed to qualitatively detect p16 proteins in formalin-fixed, paraffin embedded (FFPE) specimen sections by immunohistochemistry (IHC) staining on the Tissue-Tek Genie® Advanced Staining System. The clinical interpretation must be made in conjunction with histological examination, relevant clinical information, other diagnostic tests and proper controls by a qualified pathologist.

Limitations

This product has been optimized for use with the default protocol for this antibody on the Tissue-Tek Genie Advanced Staining System, using Tissue-Tek Genie® reagents and FFPE specimen sections. Staining quality may diminish when used with other systems and/or reagents.

This product is not available in the U.S.A.

Summary and principle

P16, also named p16 (INK4a), is a cyclin-dependent kinase inhibitor that plays a role in regulating the cell cycle and functions as a tumor suppressor. When over-expressed it can be detected in the nucleus and cytoplasm. Anti-p16 antibody is a useful tool for classifying cervical dysplasia and differentiating cervical adenocarcinoma from endometrial adenocarcinoma when used with a panel of antibodies.

The Tissue-Tek Genie anti-p16 Mouse Monoclonal Antibody [MX007] is a primary antibody against p16

proteins and is provided in buffered saline containing 1% bovine serum albumin and 0.09% sodium azide. FFPE specimen sections are placed on positively charged slides and the paraffin is removed using the Tissue-Tek Genie® Dewax Solution (REF 8865), after which heat-induced epitope retrieval is performed using the Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744).

IHC demonstration of p16 proteins in FFPE specimen sections is achieved through use of the Tissue-Tek Genie anti-p16 Mouse Monoclonal Antibody [MX007] and the Tissue-Tek Genie® Pro Detection Kit, DAB (REF 8826). This procedure entails the sequential application of antibody and kit components as follows:

- Tissue-Tek Genie® Protein Block
- Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007]
- Tissue-Tek Genie® Peroxidase Block
- Tissue-Tek Genie® Link (binds to the primary antibody)
- Tissue-Tek Genie® Polymer HRP-Conjugate (binds to the link)
- Tissue-Tek Genie® DAB Substrate (visualizes the detected protein)

Tissue-Tek Genie® Hematoxylin (REF 8830) is then used to visualize the nuclei of cells. The IHC stained slide is cover-slipped and the FFPE specimen section reviewed using a light microscope.

Expected results

Specificity and intended use of this antibody were validated by performing IHC staining on the Tissue-Tek Genie Advanced Staining System using FFPE normal and tumor specimen sections.

In tonsil, nuclear and cytoplasmic staining is observed in scattered squamous epithelial cells in the lymphocyte rich area of the reticulated crypt epithelium and in scattered follicular dendritic cells in the germinal centers. The antibody also labels neoplastic cells in squamous cell carcinoma of the cervix but not normal cervical squamous epithelial cells.

Sensitivity and identification of the p16 proteins by this antibody may be affected by improper specimen handling. This may alter antigenicity, weaken detection and may generate false negative results.

Cellular staining pattern: nuclear and cytoplasmic

Positive tissue control: tonsil and cervical squamous carcinoma

Cautions and warnings

For professional use only. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Wear protective gloves, clothing, and eye/face protection.

Capsules filled with ready-to-use, pre-diluted, antibody are for single use only. Do not attempt to refill or add additional reagent. Discard capsule after use.

Cartridges filled with ready-to-use, pre-diluted, antibody are intended for multiple uses. Do not attempt to refill or add additional reagent. Discard cartridge when empty.

It is recommended to include appropriate controls on each specimen slide to help in identifying any deviation that might occur during the staining process.

All disposal practices must be in compliance with all Federal, State/Provincial and local laws and regulations. Refer to the SDS for further information.

Storage conditions

Store this product at 2-8°C.

Instructions for use

Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007], capsules (REF 8313-C010):

1. Place the Tissue-Tek Genie® Reagent Dispensing Area Tag (RDA-Tag) attached to the capsule into the RDA.
2. Push the capsule into the RDA with foil side down and click the attached RDA-Tag down into place on the RDA.
3. Place the RDA on the desired station of the Tissue-Tek Genie Advanced Staining System.
4. Place the slide with the specimen section on the same station, specimen section side down.
5. Assign protocol 8313 to the same station.
6. Initiate execution of protocol 8313.
7. The RDA-Tag 8313 will be scanned and registered automatically when the staining process is initiated.
8. During the primary antibody application step, the antibody will be released from the capsule into the RDA and onto the specimen section on the slide.
9. The staining protocol continues to the end.

Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007], cartridge (REF 8313-M250):

1. Prior to placing the cartridge on the carousel of the Tissue-Tek Genie Advanced Staining System, prime the cartridge by facing the nozzle downwards and gently pinching the nozzle tubing until the tubing is filled with the reagent.
2. Place the cartridge on the carousel.
3. Click the RDA-Tag 8313 into place on the RDA.
4. Place the RDA on the desired station of the Tissue-Tek Genie Advanced Staining System.
5. Place the slide with the specimen section on the same station, specimen section side down.
6. Assign protocol 8313 to the same station.
7. Initiate execution of protocol 8313.
8. The RDA-Tag 8313 and the cartridge will be scanned and registered automatically when the staining process is initiated.
9. During the primary antibody application step, the antibody will be dispensed from the cartridge into

the RDA and onto the specimen section on the slide.

10. The staining protocol continues to the end.

Material required but not supplied

The following reagents may be required for staining but are not provided:

- Tissue-Tek Genie® Dewax Solution (REF 8865)
- Tissue-Tek Genie® Wash Solution (REF 8874)
- Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744)
- Tissue-Tek Genie® Non-Immune Mouse Ig Antibody, Negative Control (REF 8604)
- Tissue-Tek Genie® Pro Detection Kit, DAB (REF 8826)
- Tissue-Tek Genie® Hematoxylin (REF 8830)

Further information can be found on the Sakura Finetek USA website at www.sakuraus.com/Genie

Order information

Product code, product name and quantity

REF 8313-C010 Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007], Ready-To-Use, 10 capsules; 1 pack.

REF 8313-M250 Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007], Ready-To-Use, 250 tests, 1 cartridge; 1 unit.

NOTE: The Safety Data Sheet (SDS) is available online on the Sakura Finetek USA website at www.sakuraus.com/SDS.html

References










1. Sano T, et al. Am J Pathol. 1998; 153:1741-1748.
2. Savone D, et al. Tumori. 2016; 102:450-458.
3. Mulvany NJ, et al. Pathology. 2008; 40:335-443.
4. Carozzi F, et al. Lancet Oncol. 2013; 14:168-176.
5. Mahajan A. Hum Pathol. 2016; 51:64-74.
6. Nishio S, et al. J Gynecol Oncol. 2013; 24:215-221.


Contact

If located within the United States, contact Sakura Finetek USA, Inc. by calling toll free **1-800-725-8723** or contact your Sakura Finetek representative or authorized distributor.

In countries, other than the United States, contact the nearest authorized Sakura Finetek instrument distributor or representative. Contact details may be found at www.sakura.com

Symbols

	Catalog number
	Batch code
	<i>in vitro</i> diagnostic medical device
	Temperature limitation
	Use by
	Manufacturer
	Consult instructions for use
	European Conformity
	Authorized representative in the European Community

Storage: 2°C  8°C







	Sakura Finetek USA, Inc. 1750 W 214 th Street Torrance, CA 90501 U.S.A.
	Sakura Finetek Europe B.V. Flemingweg 10a 2408 AV Alphen aan den Rijn The Netherlands
Made in U.S.A.	

GS-32445 Rev.A

