

# Tissue-Tek Genie®

## anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y]

### Instructions for use

#### Intended use

For *in vitro* diagnostic use.

Tissue-Tek Genie® anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y] is an antibody designed to qualitatively detect SMAD4 protein 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.

#### Summary and principle

The SMAD family 4 (SMAD4) or deleted in pancreatic cancer 4 (DPC4) is a tumor suppressor gene that is inactivated in a sub-set of pancreatic adenocarcinomas. Somatic mutations of SMAD4 have been discovered in pancreatic duct adenocarcinoma (~ 55%). Alterations in the SMAD4 gene also occur in a variety of cancers, including gastrointestinal track cancers, such as colorectal carcinoma (10-20%). Loss of nuclear staining in tumor cells, without cytoplasmic staining, indicates SMAD4 loss and is a surrogate for

SMAD4 gene mutation. Anti-SMAD4 antibody is a useful aid in differentiating high-grade pancreatic intraepithelial neoplasia and invasive pancreatic adenocarcinoma from benign/reactive pancreatic conditions when used with a panel of other antibodies.

The Tissue-Tek Genie anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y] is a primary antibody against the human SMAD4 protein 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-G001), after which heat-induced epitope retrieval is performed using the Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744-G001).

IHC demonstration of SMAD4 in FFPE specimen sections is achieved through use of the Tissue-Tek Genie anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y] and the Tissue-Tek Genie® Pro Detection Kit, DAB (REF 8826-K250). This procedure entails the sequential application of antibody and kit components as follows:

- Tissue-Tek Genie® Protein Block
- Tissue-Tek Genie® anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y]
- Tissue-Tek Genie® Peroxidase Block
- Tissue-Tek Genie® Link (binds to the primary antibody)
- Tissue-Tek Genie® Poly-HRP Conjugate (binds to the link)

- Tissue-Tek Genie® DAB  
(visualizes the detected protein)

Tissue-Tek Genie® Hematoxylin (REF 8830-M250) 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.

Predominant nuclear staining is observed in the majority of basal squamous epithelial cells of tonsil while negative or faint staining is observed in superficial squamous epithelial cells. In other cells, such as tonsillar lymphocytes, mainly nuclear and some cytoplasmic staining is observed. In appendix, nuclear and cytoplasmic staining is observed in the epithelial cells of proliferative compartment of the crypts, while negative or faint staining is observed in the luminal epithelial cells. In normal pancreas, nuclear and cytoplasmic staining is observed in the acinar cells and stroma cells. Negative staining is observed in the neoplastic cells of a subset pancreatic adenocarcinomas.

Sensitivity and identification of SMAD4 protein 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: cytoplasmic and nuclear

Positive specimen control: appendix, pancreas, and pancreas or colon adenocarcinoma, tonsil

## 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-SMAD4 Rabbit Monoclonal Antibody [EP618Y], capsules (REF 8258-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 8258 to the same station.
6. Initiate execution of protocol 8258.
7. The RDA-Tag 8258 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-SMAD4 Rabbit Monoclonal Antibody [EP618Y], cartridge (REF 8258-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 8258 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 8258 to the same station.
7. Initiate execution of protocol 8258.
8. The RDA-Tag 8258 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-G001)
- Tissue-Tek Genie® Wash Solution (REF 8874-G004)
- Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744-G001)
- Tissue-Tek Genie® Non-immune Rabbit Ig Antibody, Negative Control (REF 8605-C010, 8605-M250)
- Tissue-Tek Genie® Pro Detection Kit, DAB (REF 8826-K250)
- Tissue-Tek Genie® Hematoxylin (REF 8830-M250)

Further information can be found on the Sakura Finetek USA website at [www.sakuraus.com/Genie](http://www.sakuraus.com/Genie)

## Order information

#### Product code, product name and quantity

REF 8258-C010 Tissue-Tek Genie® anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y], Ready-To-Use, 10 capsules; 1 pack.

REF 8258-M250 Tissue-Tek Genie® anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y], 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](http://www.sakuraus.com/SDS.html)

## References









1. Wilentz RE, et al. Am J Pathol. 2000; 156:37-43.
2. Wilentz RE, et al. Cancer Research. 2000; 60:2002-2006.
3. Tascilar M, et al. Am J Clin Pathol. 2001; 116:831-837.
4. McCarthy AJ, et al. J Clin Pathol. 2018; 71:661-664.
5. Ali S, et al. Diagn Cytopathol. 2007; 35:644-8.
6. Zapata M, et al. CytoJournal. 2007; 4:13.
7. Zhao M, et al. Int. J. Bio. Sci. 2018; 14:111.

## 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](http://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







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