

Tissue-Tek Genie®

anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1]

Instructions for use

Intended use

For *in vitro* diagnostic use.

Tissue-Tek Genie® anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1] is a mouse monoclonal antibody cocktail designed to qualitatively detect p40 and myosin smooth muscle 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.

Summary and principle

The Δ Np63 isoform, also known as p40, is the predominant isoform of p63 that is truncated, or lacking the N-terminal domain. p40 is a nuclear protein and a transcription factor. It is confined to basal cells of squamous epithelia and urothelium, as well as basal cells/myoepithelial cells in breast, sweat gland, salivary gland, and prostate. Recent studies have shown that

p40 is highly specific for squamous and basal cells and is superior to p63 for diagnosing lung squamous cell carcinoma. In addition, anti-p40 antibody clone BC28 was shown to be a valuable marker for the identification of urothelial carcinomas and squamous cell carcinoma of head and neck, as well as for differentiation between benign and malignant prostate glands and between breast ductal carcinoma *in situ* (DCIS) and invasive breast ductal carcinoma.

Myosin is one of the major contractile proteins in muscle and non-muscle cells. It is involved in conversion of chemical energy into mechanical work. A myosin molecule consists of two heavy chains (MHCs) and two pairs of light chains. Different isoforms of heavy chains are seen in different cell types. Smooth muscle myosin heavy chain (SMH) is encoded by the MYH11 gene. It is expressed in visceral and vascular smooth muscle cells and myoepithelial cells. SMH has been demonstrated in endothelial cells of lymph node postcapillary venules, splenic sinus lining cells, and dendritic follicular cells in lymph node germinal centers and splenic B-cell areas. SMH is expressed in the majority of smooth muscle tumors and myoepithelial tumors. Staining in the preserved myoepithelial cell layer is usually observed in DCIS but not in infiltrating carcinoma of breast, which lacks myoepithelial cells.

The Tissue-Tek Genie® anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1] is a useful aid for differentiating invasive breast carcinoma from noninvasive breast lesions such as ductal carcinoma *in situ* (DCIS) when used with a panel of other antibodies.

The Tissue-Tek Genie anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1] is a primary mouse monoclonal antibody cocktail against the human p40 and myosin smooth muscle 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-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 p40 and myosin smooth muscle in FFPE specimen sections is achieved through use of the Tissue-Tek Genie anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1] 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-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1]
- 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.

Normal tissue: nuclear staining is observed in keratinocytes of the stratified squamous epithelium of skin, cervix, esophagus, and tonsil. Nuclear staining is observed in basal cells of respiratory epithelium of the bronchus and larynx, and in basal/myoepithelial cells

of breast, sweat glands, salivary glands, and prostate. Staining is also seen in urothelial cells. In placenta, nuclear staining is observed in dispersed cytotrophoblast cells. Staining is generally not observed in other cells.

Cytoplasmic staining is observed in visceral and vascular smooth muscle cells, myoepithelial cells lining ductal structures of normal breast, and in a majority of follicular dendritic cells of tonsil germinal centers. Staining is not observed in epithelial cells in breast tissue.

Tumor tissue: nuclear staining is observed in the neoplastic cells of lung squamous cell carcinoma. No staining is observed in the neoplastic cells of lung adenocarcinoma. Nuclear staining is also observed in urothelial carcinomas and in squamous cell carcinomas of skin, esophagus, and cervix.

Cytoplasmic staining is observed in myoepithelial cells associated with DCIS, but no staining is observed in invasive breast carcinomas.

Sensitivity and identification of p40 and myosin smooth muscle proteins by this antibody cocktail 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 specimen control: breast, 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-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1], capsules (REF 8342-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 8342 to the same station.
6. Initiate execution of protocol 8342.
7. The RDA-Tag 8342 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-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1], cartridge (REF 8342-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 8342 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 8342 to the same station.
7. Initiate execution of protocol 8342.
8. The RDA-Tag 8342 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 Mouse Ig Antibody, Negative Control (REF 8604-C010, 8604-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

Order information

Product code, product name and quantity

REF 8342-C010 Tissue-Tek Genie® anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1], Ready-To-Use, 10 capsules; 1 pack.

REF 8342-M250 Tissue-Tek Genie® anti-p40 / Myosin Smooth Muscle Antibody Cocktail [BC28/SMMS-1], 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

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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



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GS-33516 Rev. A