

Tissue-Tek Genie® DUO

anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail

Instructions for use

Intended use

For *in vitro* diagnostic use.

Tissue-Tek Genie® DUO anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail is an antibody cocktail, containing one rabbit and one mouse antibody, designed to qualitatively detect human Melan A and Ki67 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 cocktail on the Tissue-Tek Genie Advanced Staining System, using Tissue-Tek Genie® reagents, specifically the Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, and FFPE specimen sections. Staining quality may diminish when used with other systems and/or reagents.

Summary and principle

Melan-A, also known as Melanoma Antigen Recognized by T-cell 1 (MART-1), is a protein associated with endoplasmic reticulum and melanosomes and expressed in melanocytes. Melan A is expressed in all normal melanocytes and is detected in 80-100% of melanomas. Ki67 is a proliferation-associated nuclear protein expressed during all active phases of the cell

cycle and is absent in resting cells. The antibody cocktail labels Melan A and Ki67 in both normal and neoplastic cells and has a cytoplasmic and nuclear staining pattern respectively. Cellular proliferation is correlated with the progression of melanoma. This antibody cocktail is useful for assessing proliferative activity of melanoma when used in a panel of antibodies.

The Tissue-Tek Genie DUO anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail contains both, an anti-Melan A rabbit monoclonal antibody against human Melan A protein and anti-Ki67 mouse monoclonal primary antibody against human Ki67 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 Melan A and Ki67 in FFPE specimen sections is achieved through use of the Tissue-Tek Genie DUO anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail and the Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit (REF 8837-K250). This procedure entails the sequential application of antibody and kit components as follows:

- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, Protein Block

- Tissue-Tek Genie® DUO anti-Melan A [EP43] /Ki67 [GM010] Antibody Cocktail
- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, Link Mouse
- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, Link Rabbit
- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, Poly HRP + AP Conjugate
- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, DAB
- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit, AP Red

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 cocktail were validated by performing IHC staining on the Tissue-Tek Genie Advanced Staining System using FFPE normal and tumor specimen sections. Melan A red cytoplasmic staining is observed in melanocytes in basal layer of epidermis and nevus cells of skin, and Ki67 brown nuclear staining is observed in some basal squamous epithelial cells of the skin. Neoplastic cells stained red for cytoplasmic Melan A and brown for nuclear Ki67 are observed in some melanoma; melanoma-infiltrating lymphocytes may stain brown for nuclear Ki67.

Sensitivity and identification of human Melan A and Ki67 proteins by these antibodies may be affected by improper specimen handling. This may alter antigenicity, weaken detection and may generate false negative results.

Cellular staining pattern: cytoplasmic for Melan A and nuclear for Ki67

Positive specimen control: melanoma, skin

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® DUO anti-Melan A [EP43] Ki67 / [GM010] Antibody Cocktail, capsules (REF 8480-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 8480 to the same station.
6. Initiate execution of protocol 8480.
7. The RDA-Tag 8480 will be scanned and registered automatically when the staining process is initiated.
8. During the primary antibody application step, the antibody cocktail 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® DUO anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail, cartridge (REF 8480-M100):

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 8480 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 8480 to the same station.
7. Initiate execution of protocol 8480.
8. The RDA-Tag 8480 and the cartridge will be scanned and registered automatically when the staining process is initiated.
9. During the primary antibody application step, the antibody cocktail 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® DUO Non-immune Mouse and Rabbit Ig Antibody Cocktail, Negative Control (REF 8482-C010, 8482-M250)
- Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit (REF 8837-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 8480-C010 Tissue-Tek Genie® DUO anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail, Ready-To-Use, 10 capsules; 1 pack.

REF 8480-M100 Tissue-Tek Genie® DUO anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail, Ready-To-Use, 100 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. Nielsen PS, et al. Mod Pathol. 2013, 26:404-413
2. Wandler A, et al. J Cutan Pathol. 2016; 43:956-962
3. Nielsen PS, et al. Am J Dermatopathol. 2011; 33:361-370.


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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