

Tissue-Tek Genie® anti-Melanosome Mouse Monoclonal Antibody [HMB45]



INTENDED USE:

For *in vitro* diagnostic use.

Tissue-Tek Genie® anti-Melanosome Mouse Monoclonal Antibody [HMB45] is designed to qualitatively detect melanosome protein in Formalin-Fixed, Paraffin Embedded (FFPE) specimen sections by immunohistochemical (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 review of 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 & PRINCIPLE:

The antibody labels melanosome in the cytoplasm of activated and neoplastic melanocytes, such as fetal and neonatal melanocyte and junctional nevi, and melanomas. Intradermal nevi and normal resting adult melanocytes are negative. Positive staining does not provide distinction between benign and malignant melanocytic proliferation. It is a useful tool for classifying melanomas and melanocytic lesions and differentiating metastatic melanomas from other poorly differentiated tumors when using with a panel of antibodies.

The Tissue-Tek Genie anti-Melanosome Mouse Monoclonal Antibody [HMB45] is a primary antibody against the human melanosome 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), after which heat-induced epitope retrieval is performed using the Tissue-Tek Genie® High pH Antigen Retrieval Solution (REF 8744). IHC demonstration of melanosome protein in FFPE specimen sections is then achieved through use of the Tissue-Tek Genie anti-Melanosome Mouse Monoclonal Antibody [HMB45] 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-Melanosome Mouse Monoclonal Antibody [HMB45]
- 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. This antibody labels the melanosome protein in the cytoplasm melanocytes in both normal and neoplastic cells.

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

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Cellular Staining Pattern: Cytoplasmic

Positive Tissue Control: Melanoma

CAUTIONS & 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 re-fill 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 re-fill 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-Melanosome Mouse Monoclonal Antibody [HMB45], Capsules (REF 8232-C010):

1. Place the Reagent Dispensing Area (RDA)-Tag attached to the Capsule into the RDA.
2. Push the Capsule into the RDA with foil side down.
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 8232 to the same station.
6. Initiate execution of Protocol 8232.
7. The RDA-Tag 8232 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 to the specimen section on the slide.
9. The staining Protocol continues to the end.

Tissue-Tek Genie® anti-Melanosome Mouse Monoclonal Antibody [HMB45], Cartridge (REF 8232-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. Place the RDA-Tag 8232 into 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 8232 to the same station.
7. Initiate execution of Protocol 8232.
8. The RDA-Tag 8232 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 to the specimen section on the slide.
10. The staining Protocol continues to the end.

Tissue-Tek Genie[®] anti-Melanosome Mouse Monoclonal Antibody [HMB45]



Materials 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.sakura-america.com/Genie

ORDER INFORMATION:

Product Code/Product Name

REF 8232-C010 Tissue-Tek Genie[®] anti-Melanosome Mouse Monoclonal Antibody [HMB45],
10 Capsules, Ready-To-Use.

REF 8232-M250 Tissue-Tek Genie[®] anti-Melanosome Mouse Monoclonal Antibody [HMB45],
1 Cartridge, 250 Tests, Ready-To-Use.

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

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

REFERENCES:

1. Yang E, et al. Blood. 1996 Jul 15;88(2):386-401.
2. Yunis J. J., et al. New Eng. J. Med. 320: 1047-1054, 1989.
3. Yunis J. J., et al. New Eng. J. Med. 316: 79-84, 1987.

SYMBOLS:

- Catalog number
- Batch code
- in vitro* 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

Shipping: 2°C 8°C



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