Melanosome/HMB-45

Mouse Monoclonal Antibody

SAM-QHD- MM100-10 tests

QHD-MM100-100 tests

Document Number: IFU-MM100-Melanosome/HMB-45, 05312018

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Source	Clone	Species	Isotype	Primary Antibody Diluent
Tissue Culture Supernatent	HMB-45	Mouse	IgG/k	NA
Epitope: Not Determined		*Species Reactivity: Human*		

Catalog Number	Description
SAM-QHD-MM45-10 tests	2 mL Ready To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform.
QHD-MM45-100 tests	15 mL Ready To Use antibody for use with StatLab Quantum HD HRP or Quantum HD AP Detection kit on fully automated StatLab Quantum HDx Platform

Intended Use For In Vitro Diagnostic.

HMB-45 (HMB-45) Mouse Monoclonal Primary Antibody is intended for laboratory use in the detection of HMB-45 in formalin-fixed, paraffin-embedded tissue stained in qualitative immunohistochemistry (IHC) testing.

The results using this product should be interpreted by a qualified pathologist in conjunction with the patient's relevant clinical history, other diagnostic tests and proper controls.

Summary and Explanation

Anti-HMB45 is a useful melanoma immunohistochemical marker that reacts with antigens present on immature melanosomes. Anti-HMB45 is useful for identifying amelanotic melanoma from other neoplastic lesions with similar morphology.[1-5]

Materials and Methods Provided

The stated primary antibody product contains reagent in a vial made for use with the StatLab Quantum HDx IHC slide stainer. The vial is equipped with an RFID tag that is ready by the slide stainer to provide product and lot specific information.

This antibody is diluted in Tris Buffer, pH 7.3-7.7, with 1% BSA and <0.1% Sodium Azide.

Reconstitution, Mixing, Dilution and Titration:

Ready-to-Use antibodies are ready-to-use and optimized for staining. No reconstitution, mixing, dilution or titration is required. Differences in tissue processing and technical procedures in the laboratory may produce significant variability in results and consequently require regular use of controls.

Materials and Reagents Needed but Not Provided

The following reagents and materials may be required for staining but are not provided with the primary antibody. Please refer to our website at: www.StatLab.com.

1. Quantum HD HRP Detection Kit (Cat. No.: QHD-U-15-HRP-KIT)
2. Quantum HD Retrieval Solution, pH 9.0 (Cat. No.: QHD-003)
3. Quantum HD Retrieval Solution, pH 6.0 (Cat. No.: QHD-002)
4. Quantum HD DS2 (Cat. No.: QHD-007)
5. Quantum HD Block (Cat. No.: QHD-006)
6. Quantum HD AP Detection Kit (Cat. No.: QHD-U-15-HRP-KIT)
7. Wash Buffer (Cat. No.: QHD-015)
8. Positive and Negative Tissue controls

Storage and Handling

Store at 2-8°C. Do NOT freeze. When stored properly, the reagents are stable to the date indicated on the label. The presence of an unusual odor or precipitate indicates that the antibody is deteriorating and should not be used. Do not use reagents beyond the expiration date printed on the vial. The user must validate any storage conditions other than these specified in the package insert.

Principles of the Procedures

Antigen detection by immunohistochemistry (IHC) is a two-step process involving first, the binding of a primary antibody to the antigen of interest, and second, the detection of bound antibody by a chromogen. The primary antibody may be used in IHC using manual techniques or using automated IHC Staining Systems.

Warnings and Precautions

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable as hazardous materials[6].
2. Sodium azide (NaN3) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing[7]
3. Specimens, before and after fixation and all materials exposed to them, should be handled as if capable of transmitting infections and disposed of with proper precautions[8].
4. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water.
5. Microbial contamination of reagents may result in an

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2090 Commerce Drive
McKinney, Texas 75069
(800) 442-3573
www.StatLab.com

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increase in nonspecific staining.

6. Incubation times or temperatures other than those specified may give erroneous results. The use must validate any such change.
7. The SDS is available upon request
8. Do not use reagents beyond the expiration date printed on the vial.
9. The user must validate any storage conditions other than these specified in the package insert

Specimen Collection and Preparation

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding[9-10].

The user is advised to validate the use of the products with their tissue specimens prepared and handled in accordance with their laboratory practices

StatLab Quantum HDx Recommended Staining Procedure:

Instrument Parameters	QHD-U3-HRP-Kit	QHD-U2-AP-Kit
Retrieval Reagent	QHD-High pH	QHD-High pH
Antibody Incubation Time	10-45 minutes	10-45 minutes

Step by Step Procedure:

1. Follow the StatLab Quantum HDx instrument instructions for setting up the reagents on the instrument
2. Load slides, antibodies, and detection kit(s) onto StatLab Quantum HDx instrument according to StatLab Quantum HDx instructions for use
3. Start the run.
4. When the staining is complete, remove the slides from instrument, rinse well with distilled water
5. Dehydrate, Clear and Coverslip

Troubleshooting:

Positive and negative controls should be run simultaneously with all patient specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact StatLab IHC Technical Support via Email at: ihctech@statlab.com or call us at (800) 442-3573.

Cellular Localization and Positive Tissue Control

Positive Tissue Control	
Tissue	Visualization
Melanoma	Cytoplasmic

Limitations of the Procedure

IHC is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can also cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue may cause variations in results[11]. Endogenous peroxidase activity or pseudo peroxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give

false positive with horseradish peroxidase systems[12]. Improper counterstaining and mounting may compromise the interpretation of results.

Performance Characteristics

The optimum antibody protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, and tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times may vary. The data sheet recommendations and protocols are based on exclusive use of products manufactured for StatLab. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

NOTE

There are no expressed or implied warranties which extend beyond this datasheet. StatLab is not liable for personal injury, property damage or economic loss caused by this product

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