

ISO 9001&13485

CERTIFIED

## Tyrosinase

Concentrated and Prediluted Monoclonal Antibody Control Number: 901-155-032415

 Catalog Number:
 CM 155 A, B, C
 PM 155 AA

 Description:
 0.1, 0.5, 1.0 ml, concentrated
 6.0 ml, prediluted

 Dilution:
 1:50-1:200
 Ready-to-use

 Diluent:
 Van Gogh Yellow
 N/A

#### Intended Use:

#### For In Vitro Diagnostic Use

Tyrosinase [T311] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of tyrosinase protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

#### **Summary and Explanation:**

Tyrosine is a key enzyme involved in the initial stages of melanin biosynthesis. Studies have shown tyrosinase to be a more sensitive marker when compared to HMB -45 and MART-1. It has also been shown to label a higher percentage of desmoplastic melanomas than HMB-45. However, both tyrosinase and MART-1 negative staining was seen in those variants without an epidermal component. Unlike HMB-45, tyrosinase or MART-1 does not discriminate between activated or resting melanocytes. Other studies have shown tyrosinase to be a very specific marker for melanomas, and did not cross react with any tumors or normal tissues tested. In conclusion, tyrosinase is shown to be a superior melanoma marker when compared to HMB-45.

#### **Principle of Procedure:**

Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. A secondary antibody may be applied to bind the primary antibody, followed by an enzyme labeled polymer; or an enzyme labeled polymer may be applied directly to bind the primary antibody. The detection of the bound primary antibody is evidenced by an enzyme-mediated colorimetric reaction.

Source: Mouse monoclonal

Species Reactivity: Human; others not tested

### Clone: T311

Isotype: IgG2a

Total Protein Concentration: ~10 mg/ml. Call for lot specific Ig concentration.

Epitope/Antigen: Tyrosinase

Cellular Localization: Cytoplasm

Positive Control: Melanoma

## **Known Applications:**

Immunohistochemistry (formalin-fixed paraffin-embedded tissues)

Supplied As: Buffer with protein carrier and preservative

### Storage and Stability:

Store at 2°C to 8°C. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

## Protocol Recommendations (manual use):

Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.

Pretreatment Solution (recommended): Reveal

#### **Pretreatment Protocol:**

Heat Retrieval Method:

Retrieve sections under pressure using Biocare's Decloaking Chamber, followed by a wash in distilled water; alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 10 minutes then wash in distilled water.

OAI 155 T60 60 tests, prediluted

Ready-to-use N/A

#### Protocol Recommendations (manual use) Cont'd:

**Protein Block (Optional):** Incubate for 5-10 minutes at RT with Biocare's Background Punisher.

Primary Antibody: Incubate for 15-30 minutes at RT.

Probe: Incubate for 10 minutes at RT with a secondary probe.

Polymer: Incubate for 10 minutes at RT with a tertiary polymer.

### Chromogen:

Incubate for 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Biocare's Warp Red.

## Counterstain:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

## **Technical Note:**

This antibody has been standardized with Biocare's MACH 4 detection system. It can also be used on an automated staining system and with other Biocare polymer detection kits. Use TBS buffer for washing steps.

## Protocol Recommendations (ONCORE Automated Slide Staining System):

OAI155 is intended for use with the ONCORE Automated Slide Staining System. Refer to the ONCORE Automated Slide Staining System User Manual for specific instructions on its use. Protocol parameters in the ONCORE Automated Slide Stainer Protocol Editor should be programmed as follows:

## Protocol Name: Tyrosinase

Protocol Template (Description): Ms HRP Template 1 Dewaxing (DS Option): DS2 Antigen Retrieval (AR Option): AR2, low pH; 101°C Reagent Name, Time, Temp.: Tyrosinase, 30 min., 25°C

### Limitations:

The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to: fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocol are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

## **Quality Control:**

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2). CLSI Wayne, PA, USA (www.clsi.org). 2011.

#### **Troubleshooting:**

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.



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#### **Precautions:**

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN<sub>3</sub>) 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. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (5)

2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. 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. (6)

3. Microbial contamination of reagents may result in an increase in nonspecific staining.

4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.

5. Do not use reagent after the expiration date printed on the vial.

6. The SDS is available upon request and is located at http://biocare.net/support/.

## **References:**

1. Orchard GE. Comparison of immunohistochemical labelling of melanocyte differentiation antibodies melan-A, tyrosinase and HMB 45 with NKIC3 and S100 protein in the evaluation of benign naevi and malignant melanoma. Histochem J. 2000 Aug;32(8):475-81.

2. Jungbluth AA, *et al.* T311--an anti-tyrosinase monoclonal antibody for the detection of melanocytic lesions in paraffin embedded tissues. Pathol Res Pract. 2000;196(4):235-42.

3. Kaufmann O, *et al.* Tyrosinase, melan-A, and KBA62 as markers for the immunohistochemical identification of metastatic amelanotic melanomas on paraffin sections. Mod Pathol. 1998 Aug;11(8):740-6.

4. Hofbauer GF, *et al.* Tyrosinase immunoreactivity in formalin-fixed, paraffinembedded primary and metastatic melanoma: frequency and distribution. J Cutan Pathol. 1998 Apr;25(4):204-9.

5. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."

6. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.





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