Microphthalmia Transcription Factor (MiTF)

Prediluted Monoclonal Antibody
901-423-081822

BIOCARE MEDICAL

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
ONCORE Pro	OPAI 423 T60	60 tests	Ready-to-use	N/A

Intended Use:
For In Vitro Diagnostic Use
Microphthalmia Transcription Factor (MiTF) [34CA5] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of MiTF 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:
Microphthalmia transcription factor (MiTF) was recently cloned as the human homolog of the mouse microphthalmia (mi) gene product. The mi phenotype is associated with a mutant mi locus and characterized by small eyes and loss of melanin pigments. MiTF is the only nuclear melanocytic marker and is a sensitive and specific marker for malignant melanoma, including some spindle-cell variants, in cytologic specimens, and may be superior to the current standard melanocytic markers, S100 protein and HMB45 antigen. MiTF may be very valuable for the diagnosis of melanoma, including desmoplastic variants; melanocytic soft tissue tumors, such as clear cell sarcoma; and the unusual group of tumors that show combined melanocytic and myoid differentiation, the perivascular epithelioid cell family of tumors (PEComas). Microphthalmia transcription factor may be a valuable addition to the marker panel used in diagnosing melanoma, in combination with S100, HMB45, Tyrosinase and MART-1.

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. After labeling the antigen with a primary antibody, a one- or two-step detection procedure can be employed. The one-step procedure will feature an enzyme-labeled polymer that binds to the primary antibody. A two-step procedure will feature a secondary antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind to the secondary antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: 34CA5
Isotype: IgG1/kappa
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: Human MiTF
Cellular Localization: Nuclear
Positive Tissue Control: Melanoma
Known Applications:
Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Supplied As: Buffer with protein carrier and preservative
Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):
OPAI423 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: MiTF
Protocol Template (Description): Special Template (ONCORE Pro-Tect Detection Required)
Dewaxing (DS Option): DS2-50
Antigen Retrieval (AR Option): AR2, low pH; 101°C
Block Option: Buffer
Reagent Name, Time, Temp.: MiTF, 45 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 protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.

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

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_3) 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) (6)
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 into contact with sensitive areas, wash with copious amounts of water. (7)
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.

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.

References:

1. Ohsie SJ, et al. Immunohistochemical characteristics of melanoma. J Cutan Pathol. 2008 May; 35(5):433-44.
2. Sheffield MV, et al. Comparison of five antibodies as markers in the diagnosis of melanoma in cytologic preparations. Am J Clin Pathol. 2002 Dec; 118(6):930-6.
3. Dorvault CC, et al. Microphthalmia transcription factor: a sensitive and specific marker for malignant melanoma in cytologic specimens. Cancer. 2001 Oct 25; 93 (5):337-43.
4. O'Reilly FM, et al. Microphthalmia transcription factor immunohistochemistry: a useful diagnostic marker in the diagnosis and detection of cutaneous melanoma, sentinel lymph node metastases, and extracutaneous melanocytic neoplasms. J Am Acad Dermatol. 2001 Sep; 45(3):414-9.
5. Miettinen M, et al. Microphthalmia transcription factor in the immunohistochemical diagnosis of metastatic melanoma: comparison with four other melanoma markers. Am J Surg Pathol. 2001 Feb; 25(2):205-11.
6. 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."
7. 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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