SOX10 (M)

Concentrated and Prediluted Monoclonal Antibody
901-3099-010820

BIOCARE MEDICAL

Catalog Number:	ACI 3099 A, C	API 3099 AA, H	IPI 3099 G10	OAI 3099 T60	AVI 3099 G, H	VLTM 3099 G20
Description:	0.1, 1.0 mL conc.	6.0, 25 mL, RTU	10 mL, RTU	60 tests, RTU	6.0, 25 mL, RTU	20 mL, RTU
Dilution:	1:100	Ready-to-use	Ready-to-use	Ready-to-use	Ready-to-use	Ready-to-use
Diluent:	Renoir Red	N/A	N/A	N/A	N/A	N/A

Intended Use:
For In Vitro Diagnostic Use
SOX10 (M) [BC34] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of SOX10 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:
The transcription factor SRY-related HMG-Box gene 10 (SOX10) plays an important role in neural crest, peripheral nervous system, and melanocytic cell development (1-3). SOX10 is widely expressed in normal human tissues including melanocytes and breast tissue. SOX10 is also an important marker in malignant tumors such as melanoma, breast carcinoma, gliomas, and benign tumors such as schwannomas (3-6). More importantly, SOX10 has been shown to be expressed in 97-100% of desmoplastic and spindle cell melanomas and has also been shown to be expressed in 100% of nevi (1). Spindle cell and desmoplastic melanomas are rare variants of invasive cutaneous melanoma, with an annual incidence rate of approximately 2 per 100,000 (7). The majority of oligodendrogliomas and a large percentage of astrocytomas and poorly differentiated glioblastomas have also been shown to express SOX10 (3,5).

U.S. Patent 9,816,997 and patents pending.

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-, two- or three-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. The three-step detection procedure will feature a secondary antibody added to bind to the primary antibody followed by a linker antibody step for maximum binding. An enzyme-labeled polymer is then added to bind to the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.
Source: Mouse monoclonal
Species Reactivity: Human; others not tested
Clone: BC34
Isotype: IgG1
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: SOX10
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. Diluted reagents should be used promptly; any remaining reagent should be stored at 2ºC to 8ºC.

Protocol Recommendations (VALENT® Automated Slide Staining Platform):
VLTM3099 is intended for use with the VALENT. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Manager should be programmed as follows:
- DAB Chromogen Staining Option:
Deparaffinization: Deparaffinize for 8 minutes with Val DePar.
Pretreatment: Perform heat retrieval at 98°C for 60 minutes using Val AR-Hi pH, 5X (use at 1X).
Peroxidase Block: Block for 5 minutes with Val Peroxidase Block.
Protein Block (Optional): Incubate for 10-20 minutes with Val Background Block.
Primary Antibody: Incubate for 30 minutes.
Secondary: Incubate for 10 minutes with Val Mouse Secondary.
Linker: Incubate for 10 minutes with Val Universal Linker.
Polymer: Incubate for 10 minutes with Val Universal Polymer.
Chromogen: Incubate for 5 minutes with Val DAB.
Counterstain: Counterstain for 5 minutes with Val Hematoxylin.
- Red Chromogen Staining Option:
Deparaffinization: Deparaffinize for 8 minutes with Val DePar.
Pretreatment: Perform heat retrieval at 98°C for 60 minutes using Val AR-Hi pH, 5X (use at 1X).
Protein Block (Optional): Incubate for 10-20 minutes with Val Background Block.
Primary Antibody: Incubate for 60 minutes.
Polymer: Incubate for 45 min with Val Mouse AP Polymer.
Chromogen: Incubate for 15 min with Val Fast Red.
Counterstain: Counterstain for 5 minutes with Val Hematoxylin.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxide Block: Block for 5 minutes with Peroxidazed 1.
Pretreatment: Perform heat retrieval using Diva Decloaker. Refer to the Diva Decloaker data sheet for specific instructions.
Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Probe: Incubate for 10 minutes at RT with a secondary probe.
Polymer: Incubate for 10-20 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 Warp Red.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
intelliPATH FLX Automated Slide Stainer:
IPI3099 is intended for use on the intelliPATH FLX. Refer to the User Manual for specific instructions for use. When using the intelliPATH FLX, peroxide block with intelliPATH FLX Peroxidase Blocking Reagent (IPB5000) may be performed following heat retrieval.
Technical Note:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

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Rev: 062117

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Protocol Recommendations (ONCORE™ Automated Slide Staining System):

OAI3099 is intended for use with the ONCORE. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: SOX10 - OR - SOX10 AP
Protocol Template (Description): Ms HRP Template 1 - OR - Ms AP Template 1
Dewaxing (DS Option): DS2
Antigen Retrieval (AR Option): AR1, high pH; 103°C
Reagent Name, Time, Temp.: SOX10, 30 min., 25°C

Protocol Recommendations (Ventana BenchMark XT / ULTRA):

AVI3099 is intended for use with the BenchMark XT / ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:
- Using ***ultra*View on XT / ULTRA:**
Template/Detection: ultraView DAB
Pretreatment Protocol: CC1 Standard
Primary Antibody: 32 minutes, 37°C
- Using **OptiView on ULTRA:**
Template/Detection: OptiView DAB IHC
Pretreatment Protocol: CC1 32 minutes
Peroxidase: Pre Primary Peroxidase Inhibitor
Primary Antibody: 16 minutes, 36°C

Performance Characteristics:

Nuclear staining of SOX10 [BC34] was observed in 96.4% (106/110) of cases of cutaneous melanoma and 83.9% (73/87) of cases of metastatic melanoma (Table 1). Staining of SOX10 [BC34] was also observed in spindle cell melanoma (100%, 19/19), desmoplastic melanoma (96.6%, 28/29), benign nevi (100%, 20/20) and schwannomas (100%, 28/28). SOX10 [BC34] nuclear staining was observed in the expected normal tissues: oligodendrocytes in cerebrum and cerebellum, myoepithelial cells in breast and salivary glands, melanocytes in skin, and Schwann cells in peripheral nerve (Table 2).

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) (8)

Precautions Cont'd:

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. (9)
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. Mohamed A, *et al.* SOX10 Expression in malignant melanoma, carcinoma, and normal tissues. Appl Immunohistochem Mol Morphol. 2013 Dec; 21(6):506-10.
2. Pusch C, *et al.* The SOX10/Sox10 gene from human and mouse: sequence, expression, and transactivation by the encoded HMG domain transcription factor. Hum Genet. 1998 Aug; 103(2):115-23.
3. Mollaaghababa R, Pavan WJ. The importance of having your SOX on: role of SOX10 in the development of neural crest-derived melanocytes and glia. Oncogene. 2003 May 19; 22(20):3024-34.
4. Bondurand N, *et al.* Expression of the SOX10 gene during human development. FEBS Lett. 1998 Aug 7; 432(3):168-72.
5. Bannykh SI, *et al.* Oligodendroglial-specific transcriptional factor SOX10 is ubiquitously expressed in human gliomas. J Neurooncol. 2006 Jan; 76(2):115-27.
6. Britsch S, *et al.* The transcription factor Sox10 is a key regulator of peripheral glial development. Genes Dev. 2001 Jan 1; 15(1):66-78.
7. Feng Z, *et al.* Incidence and survival of desmoplastic melanoma in the United States, 1992–2007. J Cutan Pathol. 2011 Aug; 38(8):616-24.
8. 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."
9. 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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Table 1: Sensitivity and specificity was determined by testing formalin-fixed, paraffin-embedded neoplastic tissues.

Pathology	# Positive / Total Cases
Melanoma (Cutaneous)	106/110 (96.4%)
Metastatic melanoma	73/87 (83.9%)
Spindle cell melanoma	19/19 (100%)
Desmoplastic melanoma	28/29 (96.6%)
Desmoplastic/Spindle cell mixed features	3/3 (100%)
Epithelioid melanoma	2/2 (100%)
Sarcomatoid melanoma	2/2 (100%)
Plasmacytoid melanoma	2/2 (100%)
Balloon cell melanoma	2/2 (100%)
Rhabdoid melanoma	1/1 (100%)
Benign Nevus (Various)	20/20 (100%)
Schwannoma (Neurilemmoma)	28/28 (100%)

Table 2: Tissue cross-reactivity was determined by testing formalin-fixed, paraffin-embedded normal tissues.

Tissue	# Positive / Total tissues	Tissue	# Positive / Total tissues
Cerebrum	4/6*	Stomach	0/3
Cerebellum	2/3*	Small intestine	0/3
Adrenal	0/3	Colon	0/3
Ovary	0/3	Liver	0/3
Pancreas	0/3	Salivary gland	2/3*
Thyroid	0/3	Kidney	0/3
Parathyroid	0/3	Prostate	0/3
Testis	0/3	Uterus	0/3
Bone	0/3	Uterine cervix	0/3
Spleen	0/3	Skeletal muscle	0/3
Tonsil	0/3	Skin	3/3*
Thymus	0/3	Peripheral nerve	2/3*
Bone marrow	0/3	Lung	0/3
Lung	0/3	Larynx	0/3
Heart	0/3	Bladder	0/3
Esophagus	0/3	Placenta	0/3
Pituitary	0/3	Mesothelium	0/3
Breast	2/3*		

*Cerebrum and cerebellum: oligodendrocytes and some astrocytes; breast: myoepithelial cells; salivary gland: myoepithelial cells; skin: melanocytes; peripheral nerve: Schwann cells.

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