SOX10 (M) Concentrated and Prediluted Monoclonal Antibody

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). PATENT 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. 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: BC34

Isotype: IgG1

Total Protein Concentration: ~10 mg/ml. 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 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 (intelliPATH and manual use):

Peroxide Block: Block for 5 minutes with Biocare's Peroxidased

Pretreatment: Perform heat retrieval using Biocare's Diva Decloaker. Refer to the Diva Decloaker data sheet for specific instructions.

SDX10, 30 min., 25°C

Protocol Recommendations (Ventana BenchMark XT / ULTRA)

Slide Staining Systems:
AVI3099 is intended for use with the Ventana BenchMark XT / ULTRA Slide Staining Systems. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:

- Using ultraView 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

Technical Note:
This antibody, for intelliPATH and manual use, has been standardized with Biocare's MACH 4 detection system. Use TBS for washing steps.

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).

Intended Use:
For In Vitro Diagnostic Use

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901-3099-020118

Performance Characteristics Cont’d:
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 titer lists 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. 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.

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 (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. (Center for Disease Control Manual. Guide: Safety Management, NO. 24.
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.

Quality Control:

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.

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

References:

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Table 1: Sensitivity and specificity was determined by testing formalin-fixed, paraffin-embedded neoplastic tissues.
Table 2: Tissue cross-reactivity was determined by testing formalin-fixed, paraffin-embedded normal tissues.

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

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