

SATB2 [EP281]

Concentrated and Prediluted Rabbit Monoclonal Antibody
901-3225-082118

BIOCARE
M E D I C A L

Catalog Number:	ACI 3225 A, B	API 3225 AA
Description:	0.1, 0.5, ml concentrated	6.0 ml, prediluted
Dilution:	1:100	Ready-to-use
Diluent:	Renoir Red	N/A

Intended Use:

For In Vitro Diagnostic Use

SATB2 [EP281] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of SATB2 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:

SATB2 (special AT-rich sequence binding 2) is a 733-amino acid human DNA-binding protein involved in transcriptional regulation and chromatin remodeling (1,2). SATB2 protein expression in normal human tissue was found in the epithelium of the lower gastrointestinal tract (including appendix, colon, and rectum), as well as specific neurons (in the cerebral cortex and hippocampus), non-germinal center lymphoid cells, and the ductal epithelium of the testis and epididymis (3). In cancer tissues, SATB2 was shown to be almost exclusively expressed in colorectal carcinoma (3). This observation was followed by validation using colorectal cancer tissue from 9 different research cohorts (1558 localized and 252 metastatic colorectal adenocarcinoma). Using SATB2 as a solitary marker, SATB2 showed positive immunostaining in 92.4% (110 of 119) of stage I, 91.4% (402 of 440) of stage II, and 83.7% (431 of 515) of stage III/IV colorectal adenocarcinomas. The expression of SATB2 was analyzed in a prospective study of 840 cases in which CK20 was being used to reach a final diagnosis (4). As a solitary marker, SATB2 had a 93% sensitivity and 77% specificity in diagnosing colorectal carcinoma, but when used as a marker in combination with CK20 positivity and CK7 negativity the sensitivity was 83% and the specificity was 100% in determining colorectal origin (4). SATB2 may be useful in the common differentials of distinguishing adenocarcinomas of colorectal origin from those of gastric and pancreatic origin. SATB2 expression was analyzed in 1941 malignancy cases using tissue microarrays, and shown to be highly expressed in colorectal adenocarcinoma (96.8%; 121 of 125), with low expression in gastric adenocarcinoma (0%; 0 of 20) and pancreatic adenocarcinoma (4.2%; 4 of 95) (5). Additional studies have verified that SATB2 could serve as a clinically useful diagnostic marker for colorectal carcinomas, especially if used in a panel approach (5-8).

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, an enzyme labeled polymer is added to bind to the primary antibody. This detection of the bound antibody is evidenced by a colorimetric reaction.

Source: Rabbit monoclonal

Species Reactivity: Human; others not tested

Clone: EP281

Isotype: IgG

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

Epitope/Antigen: Synthetic peptide corresponding to the sequence of human recombinant SATB2 protein

Cellular Localization: Nuclear

Positive Tissue Control: Colorectal carcinoma

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:

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

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

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

Primary Antibody: Incubate for 30 minutes at RT.

Probe: N/A

Polymer: Incubate for 30 minutes at RT with a secondary-conjugated 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. Use TBS for washing steps.

Performance Characteristics:

Sensitivity, specificity and cross-reactivity are summarized in Tables 1 and 2, respectively.

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. 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

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

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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) (9)

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. (10)

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. FitzPatrick DR, *et al.* Identification of SATB2 as the cleft palate gene on 2q32-q33. *Hum Mol Genet* 2003;12:2491-2501.

2. Szemes M, *et al.* Isolation and characterization of SATB2, a novel AT-rich DNA binding protein expressed in development- and cell-specific manner in the rat brain. *Neurochem Res.* 2006 Feb;31(2):237-46.

3. Magnusson K, *et al.* SATB2 in combination with cytokeratin 20 identifies over 95% of all colorectal carcinomas. *Am J Surg Pathol.* 2011;35:937-48.

4. Dragomir A, *et al.* The role of SATB2 as a diagnostic marker for tumors of colorectal origin: results of a pathology based clinical prospective study. *Am J Clin Pathol.* 2014;141:630-8.

5. Lin F, *et al.* Cadherin-17 and SATB2 are sensitive and specific immunomarkers for medullary carcinoma of the large intestine. *Arch Pathol Lab Med.* 2014;138:1015-26.

6. Moh M, *et al.* SATB2 expression distinguishes ovarian metastases of colorectal and appendiceal origin from primary ovarian tumors of mucinous or endometrioid type. *Am J Surg Pathol.* 2016;40(3):419-32.

7. Berg KB, Schaeffer DF. SATB2 as an Immunohistochemical Marker for Colorectal Adenocarcinoma: A Concise Review of Benefits and Pitfalls. *Arch Pathol Lab Med* 2017;141:1428-33.

8. Zhang YJ, *et al.* SATB2 is a Promising Biomarker for Identifying a Colorectal Origin for Liver Metastatic Adenocarcinomas. *EBioMedicine.* 2018 Feb;28:62-9.

9. 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."

10. 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.

Table 1: Sensitivity and specificity were determined by testing formalin-fixed, paraffin-embedded diseased tissues.

Diseased Tissue Specificity and Sensitivity		
Tissue	Positive Cases	Total Cases
Breast Cancer	0	6
Colorectal Cancer	7	7
Lung Adenocarcinoma	0	1
Lung Squamous Cell Carcinoma	0	2
Melanoma	0	2
Prostate Cancer	0	5

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

Normal Tissue Cross-Reactivity		
Tissue	Positive Cases	Total Cases
Cerebral Cortex	0	1
Cerebellum	0	1
Adrenal	0	1
Ovary	0	1
Pituitary	0	1
Testis (Leydig cells)	1	1
Thyroid	0	1
Breast	0	2
Spleen	0	1
Tonsil	0	1
Thymus	0	1
Lymph Node	0	1
Lung	0	1
Heart (Myocardium)	0	1
Esophagus	0	1
Stomach	0	1
Small Intestine	1	1
Colon	1	1
Liver	0	1
Kidney	0	1
Prostate	0	4
Endomyometrium	0	1
Cervix	0	1
Fallopian Tube	0	1
Placenta	0	1
Smooth Muscle	0	1
Skeletal Muscle	0	1
Skin	0	1
Urethra	0	1
Bladder	0	1