BCA-225 [Cu-18]

Concentrated and Prediluted Monoclonal Antibody
901-3241-062222

BIOCARE MEDICAL

Available Product Formats				
Format	Catalog Number	Description	Dilution	Diluent
ONCORE Pro	OPAI 3241 T60	60 tests	Ready-to-use	N/A
UltraLine – For BenchMark	AVI 3241 G	6.0 mL	Ready-to-use	N/A

Intended Use:
For In Vitro Diagnostic Use
BCA-255 [Cu-18] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of BCA-225 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:
BCA-225 (Breast Cancer Antigen 225) is a 225 kD glycoprotein present in human breast carcinoma cells, as well as adenocarcinomas of the breast, kidney, ovary, and lung (1,2). Antibody clone Cu-18 was identified as specifically recognizing BCA-225 in breast carcinomas, in both the primary tumor and its metastatic derivatives (3,4). BCA-225 is considered to be a highly sensitive marker of mammary tissue (1,3).

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-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind 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: Cu-18
Isotype: IgG1
Protein Concentration: Call for lot specific Ig concentration.
Epitope/Antigen: BCA-225
Cellular Localization: Cytoplasmic
Positive Tissue Control: Breast cancer, lung cancer, ovarian cancer, endometrial cancer

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 (ONCORE™ Pro Automated Slide Staining System):
OPAI3241 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: BCA-225
Protocol Template (Description): Ms HRP Template 1
Dewaxing (DS Buffer Option): DS2-50
Antigen Retrieval (AR Option): AR1, high pH; 101°C
Block Option: Buffer
Reagent Name, Time, Temp.: BCA-225, 30 min., 25°C

Protocol Recommendations (Ventana BenchMark ULTRA):
AVI3241 is intended for use with the BenchMark ULTRA. Refer to the User Manual for specific instructions for use. Recommended protocol parameters are as follows:
Template/Detection: OptiView DAB IHC
Pretreatment Protocol: CC1 64 minutes
Peroxidase: Pre-Primary Peroxidase Inhibitor
Primary Antibody: 32 minutes, 42°C

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.

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) (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 into 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.

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. Mesa-Tejada R, *et al.* Immunocytochemical distribution of a breast carcinoma associated glycoprotein identified by monoclonal antibodies. Am J Pathol. 1988 Feb;130(2):305-14.
2. Loy TS, *et al.* Distribution of BCA-225 in Adenocarcinomas. An Immunohistochemical Study of 446 Cases. Am J Clin Pathol. 1991 Sep;96(3):326-9.

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References Cont'd:
3. Brown RW, *et al.* Immunohistochemical identification of tumor markers in metastatic adenocarcinoma. A diagnostic adjunct in the determination of primary site. Am J Clin Pathol. 1997 Jan;107(1):12-9.
4. Zombori T, Cserni G. Immunohistochemical Analysis of the Expression of Breast Markers in Basal-like Breast Carcinomas Defined as Triple Negative Cancers Expressing Keratin 5. Pathol Oncol Res. 2018 Apr;24(2):259-67.
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.

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

Tissue	Positive Cases	Total Cases
Breast Cancer	28	28
Colon Cancer	18	45
Lung Cancer	43	51
Prostate Cancer	23	47
Adrenocortical Carcinoma	0	1
Bladder Cancer	2	2
Osteosarcoma	0	1
Chondrosarcoma	0	1
Meningioma	1	1
Squamous Cell Carcinoma (Esophagus)	3	3
Adenocarcinoma (Stomach)	3	3
Adenocarcinoma (Small Intestine)	0	1
Kidney Cancer	3	3
Liver Cancer	1	4
Lymphoma	0	3
Adenocarcinoma (Head and Neck, Oral Cavity, Tongue)	0	1
Squamous Cell Carcinoma (Head and Neck, Oral Cavity, Tongue)	1	1
Nasopharyngeal Carcinoma	1	1
Ovary Cancer	2	3
Adenocarcinoma (Pancreas)	1	1
Adenoid Cystic Carcinoma (Head and Neck, Salivary Gland)	1	1
Squamous Cell Carcinoma (Skin)	1	1
Melanoma	0	1
Seminoma	0	1
Thyroid Cancer	2	2
Cervical Cancer	2	2
Endometrium Cancer	3	3

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

Tissue	Positive Cases	Total Cases
Cerebrum	0	3
Cerebellum	0	3
Adrenal	0	3
Ovary	0	3
Pancreas	2	3
Parathyroid	3	3
Pituitary	2	2
Testis	0	4
Thyroid	4	4
Breast	4	4
Spleen	0	3
Tonsil	3	3
Thymus	0	2
Bone Marrow	0	2
Lung	2	2
Heart	0	3
Esophagus	2	4
Stomach	4	4
Small Intestine	0	4
Colon	6	13
Liver	0	4
Salivary Gland	3	3
Kidney	4	4
Prostate	3	12
Uterus	3	4
Cervix	0	3
Skeletal Muscle	0	3
Skin	3	3
Peripheral Nerve	2	2
Linging Cells	0	3
Bladder	1	1
Head, Neck and Salivary Gland	0	1
Lymph Node	0	1

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