

# BRCA-1

Concentrated Monoclonal Antibody  
901-345-082418

**BIOCARE**  
M E D I C A L

**Catalog Number:** CM 345 A, B  
**Description:** 0.1, 0.5 mL, concentrated  
**Dilution:** 1:50  
**Diluent:** Van Gogh Yellow

## Intended Use:

For In Vitro Diagnostic Use

BRCA-1 [MS110] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of BRCA-1 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 BRCA-1 gene codes for a nuclear phosphoprotein that plays a role in maintaining genomic stability and acts as a tumor suppressor. The normal gene plays a role in repairing breaks in DNA. If a mutation occurs in this gene the repair function may become disabled thus leading to more DNA replication errors and neoplastic growth. Studies have shown that BRCA-1 may play an as yet undefined protective role in cells, as it is strongly expressed in epithelial cells undergoing high levels of proliferation in association with differentiation (3-4). Additional studies have shown that complete loss of BRCA-1 nuclear expression in breast cancer and the correlation with poor prognostic markers imply that the altered BRCA-1 phenotype may provide an added prognostic parameter for breast cancer and could be applied for a potential rapid screening technique to identify BRCA-1 mutations (1-4).

## 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. The detection of the bound antibody is evidenced by a colorimetric reaction.

**Source:** Mouse monoclonal

**Species Reactivity:** Human; others not tested

**Clone:** MS110

**Isotype:** IgG1

**Protein Concentration:** Call for lot specific Ig concentration.

**Epitope/Antigen:** BRCA-1

**Cellular Localization:** Nuclear

**Positive Tissue Control:** Breast cancer

**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 Peroxidized 1.

**Pretreatment Solution (recommended):** Diva

**Pretreatment Protocol:**

Heat Retrieval Method:

Preheat the retrieval solution to 95°C for 30 minutes and then place slides in the preheated solution if using Decloaking Chamber Pro or Decloaking Chamber Plus. If using Decloaking Chamber NxGen, place slides into the retrieval solution without preheating. Retrieve at 95°C for 40 minutes. Allow solution to cool for 20 minutes and then wash in distilled water.

## Protocol Recommendations Cont'd:

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

**Primary Antibody:** Incubate for 30-60 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 Warp Red.

**Counterstain:**

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

**Technical Notes:**

This antibody has been standardized with Biocare's MACH 2 detection system. It does not perform well with MACH 3 or MACH 4 detection systems. Use TBS buffer for washing steps.

**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 (NaN<sub>3</sub>) 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>.

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### 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. Ribeiro-Silva A, *et al.* p63 correlates with both BRCA1 and cytokeratin 5 in invasive breast carcinomas: further evidence for the pathogenesis of the basal phenotype of breast cancer. *Histopathology*. 2005 Nov; 47(5):458-66.
2. Ansquer Y, *et al.* Expression of BRCA1, HER-1 (EGFR) and HER-2 in sporadic breast cancer and relationships to other clinicopathological prognostic features. *Anticancer Res*. 2005 Nov-Dec; 25(6C):4535-41.
3. Kurebayashi J, *et al.* Loss of BRCA1 expression may predict shorter time-to-progression in metastatic breast cancer patients treated with taxanes. *Anticancer Res*. 2006 Jan-Feb; 26(1B):695-701.
4. Jarvis EM, Kirk JA, Clarke CL. Loss of nuclear BRCA1 expression in breast cancers is associated with a highly proliferative tumor phenotype. *Cancer Genet Cytogenet*. 1998 Mar; 101(2):109-15.
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.