



Epithelial Cell Adhesion Molecule Monoclonal Mouse Anti-Epithelial Cell Adhesion Molecule, Clone Ber-EP4

REF 014-1104

Ready-To-Use ■ 100 Tests/50 Tests

Concentrate ■ 1mL

INTENDED USE

IVD For in vitro diagnostic use.

Celerus monoclonal mouse anti-Epithelial cell adhesion molecule (EpCAM), clone Ber-EP4, is intended for laboratory use in identifying EpCAM antigen in normal or neoplastic tissue using light microscopy. EpCAM expression has been reported to be a possible marker of early malignancy, with expression being increased in tumor cells, and de novo expression being seen in dysplastic squamous epithelium. EpCAM can be used to distinguish between basal cell carcinomas and squamous cell carcinoma of the skin. It may be used with frozen or formalin-fixed paraffin-embedded tissues.

Positive results aid in the classification of normal and abnormal cells/tissues and serve as an adjunct to conventional histopathology. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made by a qualified individual in conjunction with the patient's clinical history and other diagnostic test results.

Refer to the Wave Instrument Operator's Manual for additional information concerning Materials Required but Not Provided; Storage; Staining Procedure; Troubleshooting; Interpretation of Staining; and General Limitations.

SUMMARY AND EXPLANATION

Epithelial Cell Adhesion Molecule (EpCAM) or epithelial specific antigen is a ~40kDa cell surface antigen is broadly distributed in epithelial cells and displays a highly conserved expression in carcinomas. These glycoproteins are located on the cell membrane surface and in the cytoplasm of virtually all epithelial cells with the exception of most squamous epithelia, hepatocytes, renal proximal tubular cells, gastric parietal cells and myoepithelial cells.

PRINCIPLE OF PROCEDURE

Immunohistochemistry is a multi-step process to identify specific cell markers within tissue biopsies or tumor specimens. The sequential steps include antigen retrieval (optional), antibody application, and antibody visualization followed by optional counterstaining. Specimens are then coverslipped and observed under light microscopy by trained personnel. Normally, multiple antibodies are tested to determine lineage and cell cycle markers. The Celerus Wave is an automated instrument that performs immunohistochemistry stains. For further information on the staining procedure, refer to the Celerus Wave Operator's Manual.

MATERIALS AND METHODS

Reagent Provided

Clone

Ber-EP4

Ig Class

IgG₁, kappa

Immunogen

MCF-7 cell line.

Ready-To-Use in Primary Antibody Cartridge

Celerus anti-EpCAM is provided with ProClin 300 as a preservative, in a Primary Antibody Cartridge (PAC), a self-contained dispenser of reagents. Each PAC contains sufficient reagent to complete 50 or 100 stained slides. PACs must remain upright to avoid spilling. PAC must be primed before first use. See Celerus Wave Operator's Manual for details.

Concentrated Antibody

Liquid

Liquid concentrated antibody is provided containing 15 mM sodium azide as a preservative and 1% bovine serum albumin as a carrier protein.

Lyophilized

Lyophilized antibody is provided containing 15mM sodium azide as a preservative. Reconstitute vial with 1.0 ml distilled water.

Dilution

The suggested dilution is 1:40–1:80. This is a guide only and users should determine their own optimal working dilutions.

SPECIFICITY

This antibody labels two polypeptides of 34 kDa and 39 kDa, respectively, corresponding to epithelial antigen.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Wave instrument
2. Wave slide rack
3. Positively-charged microscope slides, appropriately labeled
4. Timer
5. Celerus Riptide for antigen retrieval (or equivalent)
6. Celerus Target Retrieval Solution (or equivalent)
7. Slide drying chamber
8. Xylene or xylene substitute
9. Reagent alcohol or ethyl alcohol
10. Distilled or deionized water
11. TBS wash buffer, pH 7.6
12. Positive and negative tissue controls
13. Celerus Negative Control Reagent (or equivalent)
14. Mounting Medium
15. Cover slips

STORAGE AND HANDLING

Ready-to-Use PAC, Liquid Concentrated and Lyophilized Antibody

Store reagent at 2-8 °C. Do not freeze. The reagent is stable until the expiration date on the container. Do not use reagent after the expiration date, as the activity cannot be ensured.

Reconstituted Antibody

For reconstituted antibody, the reagent is stable for at least two months when stored at 4 °C. For long-term storage it is recommended that aliquots of the antibody be stored at -20 °C. Repeated freezing and thawing of the antibody should be avoided.

There are no signs to indicate instability of this reagent. To ensure a valid staining assay, the use of positive and negative tissue controls is recommended. Contact your Celerus representative if there are stability concerns prior to the expiration date.

PRECAUTIONS

1. For professional users.
2. Minimize microbial contamination of reagents or an increase in nonspecific staining may occur.
3. As with any product derived from biological sources, proper handling procedures should be used.
4. A Material Safety Data Sheet is available for professional users on request.
5. ProClin 300 is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.



R36 Irritating to eyes

R43 May cause sensitization by skin contact

S24 Avoid contact with skin

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S35 This material and its container must be disposed of in a safe way

S37/39 Wear suitable gloves and eye/face protection

S46 If swallowed, seek medical advice immediately and show this container or label.

WASTE DISPOSAL

Adhere to all local laws when disposing of the PAC.

PACKAGING DAMAGE

DO NOT USE a PAC if it is leaking, has leaked, has spilled, cannot be primed, or has visually apparent physical damage.

SPECIMEN COLLECTION AND HANDLING

Formalin-fixed paraffin embedded (FFPE) tissues, frozen tissues, or smears are suitable for use. Wave detection kits have been optimized for tissues fixed with 10% formalin. Ideally, each 4-6µ tissue section should be placed on charged slides on the lower 2/3 of the slide. Very large sections should be placed 1/4 inch below the lower end of the slide label.

Slides should be baked overnight at 37 °C, or at 60 °C for one hour.

Use standard histochemical techniques to deparaffinize processed slides. For uniformity of staining results, it is recommended that target retrieval be performed using the Celerus Riptide and Celerus Target Retrieval Solution (or equivalent) at 112 °C for 5 minutes. Avoid drying of the tissue specimen during this process. After all slides to be stained have been inserted and reagents mounted on the instrument, start the staining run.

When the slides have completed the staining run, remove them from the instrument, coverslip, and view under light microscopy.

PRODUCT-SPECIFIC LIMITATIONS

EpCAM antibody, when used on the Wave instrument, detects antigens that survive routine formalin fixation, tissue processing, and sectioning. Users who deviate from recommended test procedures are responsible for interpretation and validation of patient results.

RESULTS EXPECTED/ PERFORMANCE CHARACTERISTICS

Normal Tissues

All normal epithelial tissues are labeled by this antibody with the exception of parietal cells in gastric glands, apical cell layers in squamous epithelia, and adult hepatocytes, which are negative. The antibody does not label non-epithelial tissues.

Abnormal Tissues

This antibody labels most epithelial tumors derived from breast, esophagus, stomach, colon, rectum, pancreas, kidney, liver, lung, thyroid and salivary glands, vagina, ovary, cervix and nasopharynx.

Most mesotheliomas are not labeled by this antibody. In skin tumors, the antibody labels basal cell carcinomas and basosquamous carcinomas but not squamous cell carcinomas.

REFERENCES

Latzka U, Niedobitek G, Schwarting R, Nekarda H, Stein H. Ber-EP4: new monoclonal antibody which distinguishes epithelia from mesothelia. J Clin Pathol 1990;

Sheibani K, Shin SS, Kezirian J, Weiss LM. Ber-EP4 antibody as a discriminant in the differential diagnosis of malignant mesothelioma versus adenocarcinoma. Am J Surg Pathol 1991;15:779-84.

Beer TW, Shepherd P, Theaker JM. Ber EP4 and epithelial membrane antigen aid distinction of basal cell, squamous cell and basosquamous carcinomas of the skin. Histopathology 2000;37:218-23.

Momburg F, Moldenhauer G, Hämmerling GJ, Möller P. Immunohistochemical study of the expression of a Mr 34,000 human epithelium-specific surface glycoprotein in normal and malignant tissues. Cancer Res 1987;47:2883-91.



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