



Negative Control (NC) for Immunohistochemistry

REF 014-1003

Ready-To-Use ■ 100 Tests / 50 Tests

Concentrate ■ 1mL

INTENDED USE

IVD For in vitro diagnostic use.

Celerus Negative Control (NC) is intended for laboratory use as an aid in identification of nonspecific staining by light microscopy when performing immunohistochemistry. The reagent contains animal serum similar to that used in the formulation of Celerus primary antibodies. This Negative Control (NC) has been formulated for use with the Celerus Wave™ and Celerus primary antibodies of both mouse and rabbit origin.

Immunohistochemical staining serves 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

The Celerus Negative Control (NC) may be used to evaluate nonspecific binding of immunohistochemistry reagents to cells, tissues, or tissue components. In some tissues, nonspecific binding may occur, especially in certain neoplastic or necrotic tissues.

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

The Negative Control (NC) contains normal animal serum, diluted to a protein concentration equivalent to that of Celerus primary antibodies. This reagent includes ProClin 300 as a preservative and is provided in a Primary Antibody Cartridge (PAC); a self contained dispenser of reagents. Each PAC contains sufficient reagent to complete 100 stained slides. PAC's must remain upright to avoid spilling. PAC must be primed before first use. See Celerus Wave Operator's Manual for details.

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. Insert slides into the Wave Instrument according to the staining grid provided by the instrument software. 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

1. Rare staining of cells not of B-cell origin has been reported. Examples include a few cases of diffuse large (2/26, 7.7%) and diffuse mixed (1/12, 8.3%) non-Hodgkin's T-cell lymphomas as well as some membrane, cytoplasmic or perinuclear staining of Reed-Sternberg cells found in lymphocyte predominant Hodgkin's Disease.
2. Normal presence of L26- and keratin-positive dendritic cells found in the medulla of normal thymi and some thymomas may confound diagnosis of mediastinal tumors using the L26 antibody. Care should be taken to ensure the cell lineage when staining is interpreted.
3. Staining from poorly fixed tissue specimens, decalcified specimens treated with proteolytic digestion, or specimens handled without regard to tissue preservation may yield nonspecific staining of non-lymphoid tissues particularly in epithelium and smooth muscle.

RESULTS EXPECTED/ PERFORMANCE CHARACTERISTICS

There should be no specific staining of cells, either in normal or abnormal tissues when stained with the Negative Control (NC). Positive staining with the Negative Control (NC) indicates lack of specificity of the primary antibody or nonspecific background staining. If positive staining occurs with the Negative Control (NC), staining results on the test specimen should be considered invalid.



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