



Cytokeratin High Molecular Weight Monoclonal Mouse Anti-Cytokeratin High Molecular Weight Clone 34βE12

REF 014-1060

Ready-To-Use ■ 100 Tests/50 Tests

Concentrate ■ 1mL

INTENDED USE

IVD For in vitro diagnostic use.

Celerus monoclonal mouse anti-cytokeratin high molecular weight, clone 34βE12, is intended for laboratory use in identifying cytokeratins 1, 5, 10, and 14 using light microscopy. It may be used with frozen tissue or with formalin-fixed paraffin-embedded tissue.

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

Cytokeratin high molecular weight antibody recognizes keratins with high molecular weights and stains squamous, ductal, and other complex epithelia and carcinomas originating from these tissues. It can be used for characterizing squamous and ductal carcinomas arising from complex epithelia. The antibody also stains small-acinar lesions of the prostate gland and is of value in differentiating benign from malignant lesions.

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
34βE12

Ig Class
IgG₁ kappa

Immunogen

Solubilized keratin extracted from human stratum corneum.

Ready-To-Use in Primary Antibody Cartridge

Celerus anti-cytokeratin high molecular weight 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 1:25- 1:50. This is a guide only and users should determine their own optimal working dilutions.

SPECIFICITY

Human CD7 molecule.

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

Cytokeratin high molecular weight 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

Clone 34βE12 detects cytokeratin intermediate filament proteins 1, 5, 10 and, 14. It stained the cytoplasm of squamous epithelium and sweat ducts in skin, some pneumocytes, bronchial epithelium, and mesothelium in normal lung, and bile ducts in normal liver. It also stained ductal cells of the normal pancreas, some acinar and ductal cells of normal breast, basal epithelial cells of prostate, squamous epithelium of tonsil, some kidney tubules, and some epithelia and mesothelium of the normal small and large bowel.

Abnormal Tissues

Clone 34βE12 stained squamous cell carcinomas of the skin, breast, and lung, ductal carcinomas of the breast and pancreas, thymomas, adenosquamous carcinomas of the endometrium, gastrointestinal stromal tumors, and epithelial mesotheliomas. It reacts less strongly with cystadenocarcinomas of the ovary, lung, and colon, and stained adenocarcinomas of the endometrium and renal cell carcinomas only weakly. No staining was seen with small cell carcinomas, leiomyosarcomas, non-Hodgkin's lymphoma, and Hodgkin's lymphoma.

REFERENCES

Gown AM, Vogel AM. Monoclonal antibodies to intermediate filament proteins of human cells: Unique and cross-reacting antibodies. J Cell Biol 1982;95(2 Pt 1):414-24.

Moll R, Franke WW, Schiller DL. The catalog of human cytokeratins: Patterns of expression in normal epithelia, tumors and cultured cells. Cell 1982;31(1):11-24.

Gown AM, Vogel AM. Monoclonal antibodies to human intermediate filament proteins III. Distribution of filaments in normal human tissues. Amer J Pathol 1984;114(2):309-21.

Gown AM, Vogel AM. Monoclonal antibodies to human intermediate filament proteins III. Analysis of tumors. Amer J Clin Pathol 1985;84(4):413-24.

Brawer MK, Peehl DM, Stamey TA, Boswick DG. Keratin immunoreactivity in the benign and neoplastic human prostate. Canc Res 1985;45(8):3663-7.



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