Kappa Light Chain
Rabbit Polyclonal Antibody

REF **014-1067**

Ready-To-Use ▪ 100 Tests/50 Tests

Concentrate ▪ 1mL

INTENDED USE
IVD For in vitro diagnostic use.

Celerus rabbit polyclonal anti-Kappa Light Chain antibody, is intended for laboratory use in identifying kappa light chains in normal or neoplastic tissue using light microscopy. It may be used with frozen or 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
Individual B cells express either kappa or lambda light chains, but not both. The ratio of kappa- to lambda-producing B cells is usually about 2:1, and an irregular ratio can be a significant indicator of disease. A mixture of kappa and lambda light chain-bearing cell types suggests polyclonality and a reactive or non-neoplastic proliferation of B cells. Diseases such as multiple myeloma and B-cell lymphoma are characterized by the proliferation of monoclonal neoplastic plasma cells producing only one type of light chain. Thus, demonstration of a kappa or lambda light chain-restricted cell population can be useful in the diagnosing these diseases.

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
Rabbit polyclonal antibody to kappa light chain

Immunogen
Polyclonal kappa light chains isolated from pooled human sera.

Ready-To-Use in Primary Antibody Cartridge
Celerus anti-Kappa Light Chain 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 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 1:100– 1:200. This is a guide only and users should determine their own optimal working dilutions.

SPECIFICITY
Free kappa chains and kappa chains in intact immunoglobulin molecules.

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
Kappa Light Chain 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
In tonsils and reactive lymph nodes this antibody stains kappa light chains in the cytoplasm of plasma cells, follicle center blasts, and small lymphocytes in the follicular mantle. Langerhans' cells are negative for kappa and lambda light chains. The antibody does not stain muscle, epithelium, or nerve tissue.

Abnormal Tissues
In B-cell non-Hodgkin's lymphoma, monotypic light chain expression was seen in 81% of the cases using anti-kappa and anti-lambda antibodies (n=113).

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