Kappa (M) + Lambda (P)

Prediluted Multiplex Antibody Reagent
901-3159DS-092519

BIOCARE MEDICAL

Catalog Number:	**API 3159 DS AA**	**VLTMR 3159 G20**
Description:	6.0 mL, RTU	20 mL, RTU
Dilution:	Ready-to-use	Ready-to-use
Diluent:	N/A	N/A

Intended Use:
For In Vitro Diagnostic Use
Kappa (M) + Lambda (P) is a cocktail of mouse monoclonal and rabbit polyclonal antibodies that is intended for laboratory use in the qualitative identification of kappa and lambda immunoglobulin light chain proteins 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:
Kappa and Lambda antibodies are usually run together on two separate tissues. In normal tissue, the Kappa and Lambda cell ratio is approximately 2:1. The double stain antibody allows the investigator to simultaneously see both Kappa (M) (brown) and Lambda (P) (red) on the same tissue section, thus allowing the end-user a more accurate and easier assessment of both stains.
The antibody cocktail recognizes both kappa and lambda light chains. It is reportedly useful in the identification of myelomas, plasmacytomas, and certain non-Hodgkin's lymphomas. The most common feature of these malignancies is the restricted expression of a single light chain class. Demonstration of clonality in lymphoid infiltrates may indicate that the infiltrate is malignant.

Principle of Procedure:
This product is a primary antibody cocktail of mouse and rabbit antibodies, which may be used in a Multiplex IHC staining procedure to produce a two-color stain. Following application of the primary antibody cocktail to the tissue sample, detection is performed by separate secondary antibodies specific for each species (i.e. mouse or rabbit) of the primary antibody cocktail, which are conjugated to horseradish peroxidase (HRP) or alkaline phosphatase (AP) enzymes. Visualization is accomplished by the application of chromogenic substrates (DAB and Red), which are enzymatically activated (by HRP or AP, respectively) to produce a colored reaction product at the antigen site. The specimen may be counterstained and coverslipped. Results are interpreted using a light microscope.

Reagent Provided:
Kappa (M) + Lambda (P) is provided as a prediluted antibody cocktail of anti-kappa and anti-lambda antibodies, in buffer with carrier protein and preservative.

Antibody	anti-Kappa	anti-Lambda
Clone	L1C1	N/A
Source	Mouse monoclonal	Rabbit polyclonal
Isotype	IgG1	IgG
Epitope/ Antigen	kappa light chain	lambda light chain
Cellular Localization	Cytoplasmic	Cytoplasmic
Staining	Brown (DAB)	Red

Storage and Stability:
Store at 2ºC to 8ºC. The product is stable to the expiration date printed on the label, when stored under these conditions.

Known Applications:
immunohistochemistry (formalin-fixed paraffin-embedded tissues)
Species Reactivity: Human; others not tested
Positive Tissue Control: Tonsil or bone marrow

Protocol Recommendations (VALENT® Automated Slide Staining Platform):
VLTMR3159 is intended for use with the VALENT. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Manager should be programmed as follows:
Deparaffinization: Deparaffinize for 8 minutes with Val DePar.
Pretreatment: Perform heat retrieval at 98°C for 60 minutes using Val AR-Hi pH, 5X (use at 1X).
Enzyme: Incubate for 10 minutes with Val Zyme Pronase (1:25 mix).
Peroxidase Block: Block for 5 minutes with Val Peroxidase Block.
Protein Block: Incubate for 10 minutes with Val Background Block.
Primary Antibody: Incubate for 30 minutes.
Double Stain Detection: Incubate for 30 minutes using Val Plex 2.
Chromogen (1): Incubate for 5 minutes with Val DAB.
Chromogen (2): Incubate for 15 minutes with Val Fast Red.
Counterstain: Counterstain for 5 minutes with Val Hematoxylin.

Protocol Recommendations (intelliPATH FLX® and manual use):
Peroxide Block: Block for 5 minutes with Peroxidazed 1.
Pretreatment: Perform heat retrieval using Reveal Decloaker. Refer to the Reveal Decloaker product data sheet for specific instructions.
Protein Block: Incubate for 10 minutes at RT with Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Double Stain Detection: Incubate for 30 minutes at RT using MACH 2 Double Stain 2.
Chromogen (1): Incubate for 5 minutes at RT with Betazoid DAB.
Chromogen (2): Incubate for 5-7 minutes at RT with Warp Red. Rinse in deionized water.
Counterstain:
Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.
Technical Notes:
This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 2 Double Stain 2. Use TBS 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.

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_3) used as a preservative is toxic if

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

IVD CE

Rev: 062117

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080

Precautions Cont'd:
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 in 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.

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. Samoszuk MK, *et al.* Limitations of numerical ratios for defining monoclonality of immunoglobulin light chains in B-cell lymphomas. Diagn Immunol. 1985; 3(3):133-8.
2. Bray M, Alper MG. Lambda light chain predominance as a sign of emerging lymphoma. Am J Clin Pathol. 1983 Oct; 80(4):526-8.
3. Sobol RE, *et al.* Use of immunoglobulin light chain analysis to detect bone marrow involvement in B-cell neoplasms. Clin Immunol Immunopathol. 1982 Jul; 24(1):139-44.
4. Falini B, *et al.* Double labeled-antigen method for demonstration of intracellular antigens in paraffin-embedded tissues. J Histochem Cytochem. 1982 Jan; 30(1):21-6.
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.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

EC REP EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

IVD CE

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080