CD138 + Ki-67

Prediluted Multiplex Antibody Reagent

Control Number: 901-3169DS-090817

Catalog Number: **API 3169 DS AA**
Description: 6.0 ml, prediluted
Dilution: Ready-to-use
Diluent: N/A

Intended Use:
For In Vitro Diagnostic Use
CD138 + Ki-67 is a cocktail of mouse monoclonal and rabbit monoclonal antibodies that is intended for laboratory use in the qualitative identification of CD138 and Ki-67 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:

CD138/syndecan-1 is an excellent marker for identifying plasma cells, as CD138 is a transmembrane heparin proteoglycan present on the surface membrane of plasma cells that remains active in formalin-fixed paraffin-embedded bone marrow sections. Other hematopoietic cells, endothelial cells and lymphoplasmacytoid lymphomas in bone marrow are CD138 negative (1). CD138 is also expressed in fibroblasts, keratinocytes and normal hepatocytes (1).

The Ki-67 antibody identifies a nuclear antigen, which is associated with cell proliferation. It is found throughout the cell cycle in the G1, S, G2, and M phases; but not in the GO phase. It is commonly used to grade the proliferation index of tumors (2).

As CD138 is localized to the cell membrane, it can be paired with nuclear prognostic markers, such as Ki-67, in double-marker immunostaining reactions without overlap of the chromogenic signals. In multiple myeloma, a CD138 + Ki-67 IHC double stain was shown to be more sensitive and accurate for myeloma cell proliferation assessment than cytogenetic methods (3).

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 (Deep Space Black and Warp 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:

CD138 + Ki-67 is provided as a prediluted antibody cocktail of anti-CD138 and anti-Ki-67 antibodies in buffer with carrier protein and preservative.

Antibody	anti-CD138	anti-Ki-67
Clone	B-A38	SP6
Source	Mouse monoclonal	Rabbit monoclonal
Isotype	IgG1	IgG
Epitope/ Antigen	CD138	Ki-67
Cellular Localization	Cell membrane	Nuclear
Staining	Red (Warp Red)	Black (Deep Space)

Storage and Stability:
Store at 2ºC to 8ºC. Do not use reagent after the expiration date printed on the vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user.

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

Protocol Recommendations:

Peroxide Block: Block for 5 minutes with Biocare's Peroxidazed 1.
Pretreatment: Perform heat retrieval using Biocare's Reveal Decloaker. Refer to the Reveal Decloaker product data sheet for specific instructions.
Protein Block: Incubate for 10 minutes at RT with Biocare's Background Punisher.
Primary Antibody: Incubate for 30 minutes at RT.
Double Stain Detection: Incubate for 30 minutes at RT using Biocare's MACH 2 Double Stain 1.
Chromogen (1): Incubate for 5-7 minutes at RT with Biocare's Warp Red. Rinse in deionized water.
Chromogen (2): Incubate for 5 minutes at RT with Biocare's Deep Space Black.
Counterstain: Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water.

Technical Notes:
This antibody has been standardized with Biocare's MACH 2 Double Stain 1. Use TBS buffer 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. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

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 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) (4)
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. (5)

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Precautions Cont'd:

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. Chilosi M, *et al.* CD138/syndecan-1: a useful immunohistochemical marker of normal and neoplastic plasma cells on routine trephine bone marrow biopsies. Mod Pathol. 1999 Dec;12(12):1101-6.
2. Xu JL, *et al.* Proliferation, apoptosis, and intratumoral vascularity in multiple myeloma: correlation with the clinical stage and cytological grade. J Clin Pathol. 2002 Jul;55(7):530-4.
3. Ely S, *et al.* Cost effectiveness of cell proliferation vs. cytogenetics for risk stratification in multiple myeloma. Mod Pathol 2016 Feb; 29 (supplement 2):343A.
4. 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."
5. 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.

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