CE IVD

Mouse anti-IgG4

Cat. No.: MSK084-05 (0.5 ml Concentrate); MSG084 (6 ml Ready-to-use)

Instructions for use

Intended use
This antibody is designed for the specific localisation of IgG4 in formalin-fixed, paraffin-embedded tissue sections. Anti-IgG4 antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	human IgG4
Clone:	ZSIGG4
Isotype:	Mouse IgG1 kappa
Species reactivity:	Human +, others not tested

Summary and Description
IgG4-related scleroting disease is a systemic disease characterised by an increased IgG4 level in the serum, sclerosing fibrosis and diffuse lymphoplasmocytic infiltration with many IgG4-positive plasma cells. Since the affected patients usually respond positively to steroid treatment it is important to recognize the disease and to differentiate if from look-alikes (such as lymphoma) which need other treatments. Clinical manifestations are observed in pancreas, bill duct, gall bladder, lachrymal and salivary gland, retroperitoneum, kidney, lung, breast, thyroid, and prostate.
Immunohistochemical analyses of IgG4-associated scleroting disease not only show significantly more IgG4-positive plasma cells in affected tissues but also significantly increased IgG4/IgG-ratios. Typical values are >30%. The detection of IgG4-positive plasma cells is also considered to be useful for differentiation of auto-immune pancreatitis (AIP) from pancreas carcinoma.

Reagent provided
Mouse monoclonal antibody from cell culture supernatant in PBS pH 7.4 with carrier protein and preservative for stabilisation in the following formats:

Concentrate:	0.5 ml	(Cat. No. MSK084-05)
Ready-to-use:	6 ml	(Cat. No. MSG084)

Dilution of primary antibody
Dilution of Zytomed Systems' concentrated antibody depends on the detection system used. The final working dilution must always be determined by the user. The validation of staining protocol should be done by an experienced specialist. For Zytomed Systems' recommendations see chapter 'Staining procedure'.

Storage and handling
The antibody should be stored at 2-8°C without further dilution.
Dilutions of the concentrated antibody should be done in a suitable antibody dilution buffer (e.g. ZUC025 from Zytomed Systems). The diluted antibody should be stored at 2-8°C after use. Stability of this working solution depends on various parameters and has to be confirmed by appropriate controls. The antibody provided is suitable for use until the expiry date indicated on the label, if stored at 2-8°C. Do not use product after the expiry date.
Positive and negative controls should be run simultaneously with all specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Zytomed Systems' technical support or your local distributor.

Precautions
Use through qualified personnel only.
Wear protective clothing to avoid contact of reagents and specimens with eye, skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with large amounts of water.
Microbial contamination of the reagent must be avoided, since otherwise non-specific staining may occur.
Sodium azide (NaN_3), used for stabilisation, is not considered hazardous material in the concentration used. Reaction of sodium azide with lead or copper in drainage pipes can result in the formation of highly explosive metallic azides. Sodium azide should be discarded in a large volume of running water to avoid formation of deposits. Material safety data sheets (MSDS) are available upon request.

Staining procedure for formalin-fixed paraffin sections
Refer to the following table for conditions specifically recommended for this antibody. Also refer to detection system data sheets for guidance on specific staining protocols or other requirements.

Parameters	Zytomed Systems recommendations
*Pre-treatment	Enzymatic or Heat Induced Epitope Retrieval (for example in Citrate Buffer pH 6.0) *Remark: Enzymatic epitope retrieval often leads to better staining results.*
*Control tissue	Tonsil
*Working dilution	1:100-1:500 (for concentrates)
*Incubation time	30 - 60 minutes

Quality control
The recommended positive control tissue for this antibody is tonsil. We recommend carrying out a positive and a negative control with every staining run. Please refer to the instructions of the detection system for guidance on general quality control procedures.

Troubleshooting
If you observe unusual staining or other deviations from the expected results please read these instructions carefully, refer to the instructions of the detection system for relevant information or contact your local distributor.

Expected results
This antibody stains positive in the cytoplasm of cells in formalin-fixed, paraffin-embedded tissue sections. Further details about the expression pattern of IgG4 can be found in the chapter 'Summary and Description'. Interpretation of the staining results is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic procedure.

Limitations of the Procedure
Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining, for example variations in fixation and embedding or the inherent nature of the tissue can cause inconsistent results (Nadji and Morales, 1983). Endogenous peroxidase, pseudoperoxidase activity in erythrocytes or biotin may cause non-specific staining depending on the detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive results with HRP (horse radish peroxidase) detection systems (Omata *et al*, 1980). Inadequate counterstaining and mounting can influence the interpretation of the results.
Zytomed Systems warrants that the product will meet all requirements described from its shipping date until the expiry date is reached, if the product is stored and utilised as recommended. No additional guarantees can be given. Under no circumstances shall Zytomed System be liable for any damages arising out of the use of the reagent provided.

Performance characteristics
Zytomed Systems has conducted studies to evaluate the performance of the antibody for use with a standard detection system. The product has been found to be sensitive and specific to the antigen of interest with minimal or no cross-reactivity.

Bibliography

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Explanations of the symbols on the product label
Symbols are used in accordance with ISO 15223-1. Further symbols on the product label might be:

GSH07: Warning / Attention

RUO For Research Use Only