CE IVD

Rabbit anti-TFE3

Cat. No.: RBK066-01 (0.1 ml Concentrate)

Instructions for use

Intended use
This antibody is designed for the specific localisation of TFE3, in formalin-fixed, paraffin-embedded tissue sections. Anti-TFE3 antibody is intended for in vitro diagnostic use.

Specifications

Specificity:	Human TFE3
Clone:	ZSTFE03
Isotype:	Rabbit IgG
Species reactivity:	Human +, others not tested.

Summary and Description
The transcription factor E3 (TFE3), a member of the helix-loop-helix family of transcription factors, is weakly expressed in many cell types. The TFE3 gene appears to be involved in chromosomal translocations in some cancers. For example, TFE3 is a sensitive and specific immunohistochemical marker for Xp11 translocation in renal cell carcinomas leading to marked nuclear overexpression of the resulting TFE3 fusion protein compared to wild-type TFE3. Xp11.2 translocation carcinoma is the most common type of renal cell carcinoma in children but is much less common in adults.
A chromosomal rearrangement of 17q25 and Xp11.2 is characteristic of alveolar soft-tissue sarcomas (ASPS). The resulting fusion gene ASPSCR1-TFE3 is responsible for an aberrant transcription factor which is believed to favour pathogenesis.

Reagent provided
Rabbit monoclonal antibody in buffer with carrier protein and preservative for stabilisation in the following formats:
Concentrate: 0.1 ml (Cat. No. RBK066-01)

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 elaboration 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. The 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. A material safety data sheet (MSDS) for the pure substance is 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	Heat Induced Epitope Retrieval (for example in Citrate Buffer pH 6.0)
*Control tissue	Testis or renal cell carcinoma with Xp11.2-translocation
*Working dilution	1:50 - 1:200
*Incubation time	30 - 60 minutes

Quality control
The recommended positive control tissues for this antibody are testis or renal cell carcinoma with Xp11.2-translocation. 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 nuclei but also in part in the cytoplasm of formalin-fixed, paraffin-embedded tissue sections. Further details about the expression pattern of TFE3 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
Argani P. Am J Clin Pathol 126:332-4, 2006
Lazar AJ et al. Histopathol 55:750-5, 2009
Lin G et al. Arch Pathol Lab Med 139:106-21, 2015
Nadji M and Morales AR. Ann N.Y. Acad Sci 420:134-139, 1983
Omata M *et al.* Am J Clin Pathol 73:626-632, 1980

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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