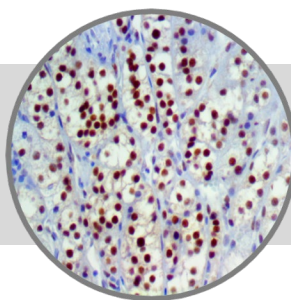


TFE3, RMab**Clone: EP285**

Rabbit Monoclonal


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Inset: IHC of TFE3 on a FFPE Testicular Cancer Tissue

Intended Use

For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical applications on formalin-fixed paraffin-embedded tissues (FFPE), frozen tissue sections and cell preparations. Interpretation of results should be performed by a qualified medical professional.

* The TFE3 antibody, clone EP285, has been manufactured using Epitomics RabMab® technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen

A synthetic peptide corresponding to residues of human TFE3 protein.

Summary and Explanation

Transcription factor E3 is a protein that in humans is encoded by the TFE3 gene. TFE3, a member of the helix-loop-helix family of transcription factors, binds to the mu-E3 motif of the immunoglobulin heavy-chain enhancer and is expressed in many cell types. A proportion of renal cell carcinomas (RCC) that occur in young patients are associated with translocations involving the TFE3 gene, which results in gene fusions. Subsets of papillary renal cell carcinomas, a t(X;1)(p11;q21) chromosome translocation has been repeatedly reported and is thought to be the cause of this cancer. As a result of the translocation, the transcription factor TFE3 on the X chromosome becomes fused to this gene on chromosome 1. The fused gene results in the fusion of N-terminal proline-rich region of the protein encoded by this gene to the entire TFE3 protein.

The Xp11.2 translocation represents the most common type of RCC in children but is less frequent on a percentage basis in adults. Morphologically, these cancers frequently show papillary architecture and clear cytoplasm, frequently have associated psammoma bodies and under-express epithelial markers such anti-cytokeratin and anti-EMA compared with typical adult type RCC. TFE3 is the most sensitive and specific immunohistochemical marker for the RCC Xp11.2 translocation, which reflects over-expression of the resulting fusion proteins relative to native TFE3. The Xp11.2 renal cell carcinoma has been recently established as a tumor affecting 15% of RCC patients <45 years. Many patients present with advanced stage with frequent lymph node metastases. Histologically, Xp11.2 RCC is characterized by mixed papillary nested/alveolar growth pattern and tumor cells with clear and/or eosinophilic, voluminous cytoplasm. Neoplastic cells show intense nuclear immunoreactivity to TFE3, while focal immunostaining for melanocytic markers, including MART-1/ Melan A in some cases, are also noted. The behavior of Xp11.2 RCC in children and young adults is considered as indolent even when diagnosed at advanced stage, including lymph node metastasis. However, Xp11.2 RCC in older patients behaves in a more aggressive fashion. Therapy includes nephrectomy with extended lymphadenectomy. Alveolar soft part sarcoma (ASPS) is a malignancy with low incidence, but with poor prognosis if misdiagnosed. Immunohistochemical assay using TFE3 antibody has been shown to be a sensitive technique for ASPS diagnosis.

Antibody Type	Rabbit Monoclonal	Clone	EP285
Isotype	IgG	Reactivity	Paraffin, Frozen
Localization	Nuclear	Control	Testis, Adrenal, Kidney, Testicular Cancer, RCC with Xp11.2 translocation, Alveolar Soft Part Sarcoma
Species Reactivity		Human	

Presentation

TFE3 is a rabbit monoclonal antibody derived from cell culture supernatant that is concentrated, dialyzed, filter sterilized and diluted in buffer pH 7.5, containing BSA and sodium azide as a preservative.

<i>Catalog No.</i>	<i>Antibody Type</i>	<i>Dilution</i>	<i>Volume/Qty</i>
BSB 3225	Tinto Prediluted	Ready-to-Use	3.0 mL
BSB 3226	Tinto Prediluted	Ready-to-Use	7.0 mL
BSB 3227	Tinto Prediluted	Ready-to-Use	15.0 mL
BSB 3228	Concentrated	1:50 - 1:200	0.1 mL
BSB 3229	Concentrated	1:50 - 1:200	0.5 mL
BSB 3230	Concentrated	1:50 - 1:200	1.0 mL

Control Slides Available

<i>Catalog No.</i>	<i>Quantity</i>
BSB 3231	5 slides

Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN₃) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as laboratory coat, goggles and gloves when handling reagents.
4. Dispose of unused solution with copious amount of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).
8. For additional safety information refer to Safety Data Sheet for this product.
9. For complete recommendations for handling biological specimens, please refer to the CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories" (see References in this document).

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Stability

This product is stable up to the expiration date on the product label. Do not use after expiration date listed on package label. Temperature fluctuations should be avoided. Store appropriately when not in use, and avoid prolonged exposure to room temperature conditions.

Specimen Preparation

Paraffin sections: The antibody can be used on formalin-fixed paraffin-embedded (FFPE) tissue sections. Ensure tissue undergoes appropriate fixation for best results. Pre-treatment of tissues with heat-induced epitope retrieval (HIER) is recommended using Bio SB ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023), ImmunoDNA Retriever with EDTA (BSB 0030-BSB 0033) or ImmunoDNA Digestor (BSB 0108-0112). See reverse side for complete protocol. Tissue should remain hydrated via use of Bio SB Immuno/DNA Washer solutions (BSB 0029 & BSB 0042).

Frozen sections and cell preparations: The antibody can be used for labeling acetone-fixed frozen sections and acetone-fixed cell preparations.

Staining Procedure

- Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively charged slides such as Bio SB Hydrophilic Plus Slides (BSB 7028).
- Air dry for 2 hours at 58° C.
- Deparaffinize, dehydrate and rehydrate tissues.
- Submerge tissues to heat induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).
- Any of three heating methods may be used:
 - TintoRetriever Pressure Cooker or Equivalent**
Place tissues/slides in a staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA, and place on trivet in the pressure cooker. Add 1-2 inches of distilled water to the pressure cooker and turn heat to high. Incubate for 15 minutes. Open and immediately transfer slides to room temperature.
 - TintoRetriever PT Module or Water Bath Method**
Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA at 95°-99° C. Incubate for 30-60 minutes.
 - Conventional Steamer Method**
Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA in a steamer, cover and steam for 30-60 minutes.
- After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
- For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
- Wash slides with ImmunoDNA washer or DI water.
- Continue IHC staining protocol. Wash slides between each step with ImmunoDNA washer solution.

Abbreviated Immunohistochemical Protocol

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP
Peroxidase/AP Blocker	5 min.	5 min.	5 min
Primary Antibody	30-60 min.	30-60 min.	30-60 min.
1st Step Detection	10 min.	30-45 min.	15 min.
2nd Step Detection	10 min.	Not Applicable	15 min.
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.
Counterstain / Coverslip	Varies	Varies	Varies

Mounting Protocols

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMunter (BSB 0169-0174) or organic solvent based resin such as PermaMunter (BSB 0094-0097), refer to PI0174 or PI0097.









Product Limitations

Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues, dilution factor of antibody, retrieval method utilized and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a qualified medical professional.

References

- Puck JM, et al. A high-frequency RFLP at the human TFE3 locus on the X chromosome. *Nucleic Acids Res.* 1991; 19 (3): 684.
- Henthorn PS, et al. The gene encoding human TFE3, a transcription factor that binds the immunoglobulin heavy-chain enhancer, maps to Xp11.22. *Genomics.* 1992; 11 (2): 374-8.
- Kuroda N., et al. Review of renal carcinoma associated with Xp11.2 translocations/TFE3 gene fusions with focus on pathobiological aspect. *Histol Histopathol.* 2012 Feb;27(2):133-40.
- Pang LJ, et al. Alveolar soft part sarcoma: a biomarker diagnostic strategy using TFE3 immunoassay and ASPL-TFE3 fusion transcripts in paraffin-embedded tumor tissues. *Diagn Mol Pathol.* 2008 Dec;17(4):245-52.
- U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. Supplement / Vol. 61, January 6, 2012.

Symbol Key / Légende des symboles/Erläuterung der Symbole

	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands		Storage Temperature Limites de température Zulässiger Temperaturbereich		Manufacturer Fabricant Hersteller		Catalog Number Référence du catalogue Bestellnummer
	In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum		Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten		Expiration Date Utiliser jusque Verwendbar bis		Lot Number Code du lot Chargenbezeichnung

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69 Santa Felicia Dr., Santa Barbara, CA 93117, USA
Tel. (805) 692-2768 | Tel. (800) 561-1145 | Fax. (805) 692-2769
E-mail: sales@biosb.com | Website: www.biosb.com