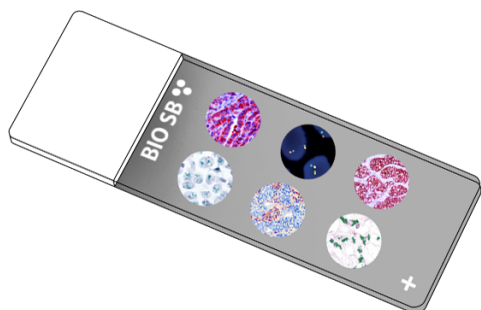


## TFE3 Control Slides



### Intended Use

For In Vitro Diagnostic Use.

### 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 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 renal cell carcinomas 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 renal cell carcinomas. TFE3 is the most sensitive and specific immunohistochemical marker for the renal cell carcinomas 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 renal cell carcinomas patients <45 years. Many patients present with advanced stage with frequent lymph node metastases. Histologically, Xp11.2 renal cell carcinomas are 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 renal cell carcinomas in children and young adults is considered as indolent even when diagnosed at an advanced stage, including lymph node metastasis. However, Xp11.2 renal cell carcinomas in older patients behave 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.

### Presentation

Five slides of TFE3 positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

<i>Catalog No.</i>	<i>Quantity</i>
BSB-9404-CS	5 slides
BSB 3231	5 slides

**Storage** Store at 20-25°C

### Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.
2. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.
4. Dispose of unused solution with copious amounts of water.
5. 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).

### Stability

**This product is stable up to the expiration date on the product label.**  
Do not use after expiration date listed on package label.

### IHC Protocol

1. Subject 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).

2. Any of three heating methods may be used:

#### a. 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.

#### b. 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.

#### c. 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.

3. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
4. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.
5. Wash slides with ImmunoDNA washer or DI water.
6. 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

### Abbreviated IF Protocol

Step	Incubation Time
Rinse slides in IF wash buffer	5 minutes
Drain and wipe excess IF wash buffer off slide	
Conduct remaining steps in the dark	
Apply Antibody	30-60 minutes
Rinse with 3 changes of IF wash buffer	3x15 minutes each
Coverslip with IF mounting medium	

### 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

1. Puck JM, et al. A high-frequency RFLP at the human TFE3 locus on the X chromosome. Nucleic Acids Res. 1991; 19 (3): 684.
2. 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.
3. 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.
4. 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.
5. 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.  
<https://www.cdc.gov/mmwr/pdf/other/su6101.pdf>

### Symbol Key / Légende des symboles/Erläuterung der Symbole

<b>EC REP</b>	QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	 Storage Temperature Limites de température Zulässiger Temperaturbereich	 Manufacturer Fabricant Hersteller	<b>REF</b>	Catalog Number Référence du catalogue Bestellnummer
<b>IVD</b>	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 jusqu'à Verwendbar bis	<b>LOT</b>	Lot Number Code du lot Chargenbezeichnung