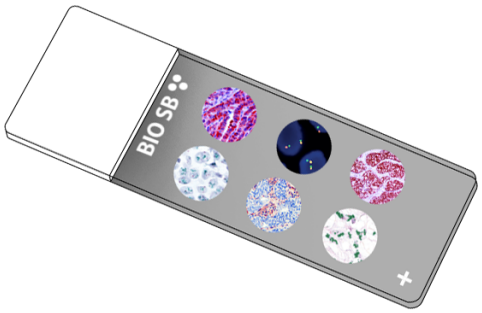
pan-TRK Control Slides

CE IVD



Intended Use
For In Vitro Diagnostic Use.

Summary and Explanation
Neurotrophic tyrosine kinase (Neurotrophic tyrosine kinase) proto-oncogene family codes for proteins Trk A, Trk B, and Trk C, which participate in pathways of neuron cell growth, differentiation, signaling, and survival. The transmembrane neurotrophic receptors are activated by neurotrophins (Nerve Growth Factor, Brain-Derived Growth Factor, and neurotrophins 3/4/5) and in turn the TRKs activate MAPK, AKT, and Phospholipase C pathways. Non-fusion alterations in Neurotrophic tyrosine kinase have been found in 14% of tested cancers. neurotrophic tyrosine kinase staining can be cytoplasmic, nuclear (as in Neurotrophic tyrosine kinase-ETV6 and Neurotrophic tyrosine kinase-LMNA fusions), or membranous (in Neurotrophic tyrosine kinase-TMP3/4) depending on the fusion pair. Neurotrophic tyrosine kinase fusions result in Neurotrophic tyrosine kinase3-ETV6 pairs in 90% of cases, most commonly found in Carcinomas and Sarcomas of the Mammary and Salivary Secretory Glands. Neurotrophic tyrosine kinase gene fusions are also found in Brain primary tumors and metastases, Lung, Breast, Papillary Thyroid Carcinoma, Colorectal and Pancreatic cancer. Neurotrophic tyrosine kinase mesenchymal tumors have multiple morphological features and coexpression of S100, CD34, and Neurotrophic tyrosine kinase.

Presentation
Five slides of pan-TRK positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

Catalog No.	*Quantity*
BSB-9328-CS	5 slides
BSB-3742-CS	5 slides
BSB-2376-CS	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 PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (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. Brčić I, Godschachner TM, Bergovec M, et al. Broadening the spectrum of Neurotrophic tyrosine kinase rearranged mesenchymal tumors and usefulness of pan-TRK immunohistochemistry for identification of Neurotrophic tyrosine kinase fusions [published online ahead of print, 2020 Aug 28]. Mod Pathol. 2020;10.1038/s41379-020-00657-x. doi:10.1038/s41379-020-00657-x2. Okamura R, Boichard A, Kato S, Sicklick JK, Bazhenova L, Kurzrock R. Analysis of Neurotrophic tyrosine kinase Alterations in Pan-Cancer Adult and Pediatric Malignancies: Implications for Neurotrophic tyrosine kinase-Targeted Therapeutics. JCO Precis Oncol. 2018;2018:PO.18.00183. doi:10.1200/PO.18.001833. Drilon A. TRK inhibitors in TRK fusion-positive cancers. Ann Oncol. 2019;30(Suppl_8):viii23-viii30. doi:10.1093/annonc/mdz2824. Hechtman JF, Benayed R, Hyman DM, et al. Pan-Trk Immunohistochemistry Is an Efficient and Reliable Screen for the Detection of Neurotrophic tyrosine kinase Fusions. Am J Surg Pathol. 2017;41(11):1547-1551. doi:10.1097/PAS.0000000000009115. Lange AM, Lo HW. Inhibiting TRK Proteins in Clinical Cancer Therapy. Cancers (Basel). 2018;10(4):105. Published 2018 Apr 4. doi:10.3390/cancers100401056. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe WorkPractices 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

EC REP QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	Storage Temperature Limites de température Zulässiger Temperaturbereich	Manufacturer Fabricant Hersteller	REF Catalog Number Référence du catalogue Bestellnummer
IVD 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 Lot Number Code du lot Chargenbezeichnung

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