

ALK/EML del-TECT™ Four Color

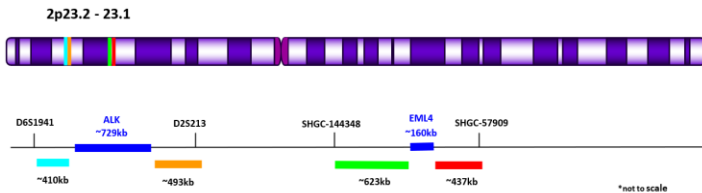
FISH Probe
902-OPPR7328-020322

Catalog Number: **OPPR7328 T30**
Description: **Prediluted FISH Probe**

Intended Use:
For Research Use Only. Not for use in diagnostic procedures.

Summary & Explanation:
A study discovered the existence of a fusion gene in 3%-7% of non-small-cell lung cancer (NSCLC), almost entirely in adenocarcinoma patients. The novel fusion comprising portions of the echinoderm microtubule-associated-protein-like 4 (EML4) gene and the anaplastic lymphoma kinase (ALK) gene resulted from a small inversion within chromosome 2p, and appears to be mutually exclusive of EGFR and KRAS mutations (1,2).

Principle of Procedure:
To identify gene rearrangements on chromosome 2 involving the ALK and EML gene. The two probes flanking the ALK gene are a telomeric aqua ALK probe (~410 kb in size) and a centromeric orange probe (~493kb in size). The two probes flanking the EML4 gene are a telomeric green probe (~ 623kb in size) and a centromeric red probe (~ 437kb in size).



Species Reactivity: Human


Known Application: Fluorescence In-situ Hybridization (FISH) on formalin-fixed paraffin-embedded (FFPE) tissues

Supplied As: Probe in hybridization buffer

Reconstitution, Dilution and Mixing:
ALK/EML del-TECT Four Color™ Four Color FISH Probe is provided ready-to-use. **Bring the vial to room temperature 30 minutes prior to EACH use and MIX WELL by shaking vigorously by hand for 3 minutes in different orientations. If vial volume is 1mL or less, mix using a pipette for 20 aspirations.**

Materials and Reagents Required but Not Provided:
Reagents and materials, such as detection kits and ancillary reagents are not provided. Refer to the ONCORE Pro FISH Kit (OPPR6064K) and the ONCORE Pro ISH Dewax Kit (OPRI6020K) datasheets. DAPI (120ng/mL) solution is also required for counterstaining. Call Technical Support for additional information on reagents and instrument accessories.

Storage and Stability:
Store probe at -20°C and away from light. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date.

 Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

Instructions for Use:
OPPR7328 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:
Protocol Name: ALK/EML 4CP
Protocol Template (Description): PathoFISH Template 1
Reagent Name, Time, Temp.: FISHzyme*, 35 min., 37°C

*FISHzyme (OPPR6066) is a part of ONCORE Pro FISH Kit (OPPR6064K).
Incubation time of FISHzyme may be adjusted based on the tissue type and tissue fixation.

Slides should be baked offline for 1 hour at 60°C prior to loading onto the instrument.

The ONCORE Pro Baking Slides Before Staining setting should be selected and set for 10 min at 60°C to improve tissue retention.
Post ONCORE Pro FISH staining processing:
1. Gently rinse slides in TBS buffer, followed by a gentle rinse in DI water.
2. Place the slide rack in a dark cabinet to air dry.
3. Apply 1-2 drops of Fluoro Care Mounting Media (FP001) under a suitable size coverslip, e.g., 22x40 mm.

Technical Notes:
1. FISH runs should not be delayed as the probe will separate.
2. Biocare Medical Four Color FISH probes are optimized to provide the best signal performance using optical filters that can accommodate the excitation/emission wavelengths specified below. Using filters outside these spectral specifications may produce sub-optimal results.

Fluorophore	Excitation (nm)	Emission (nm)
AQUA	426	498
GREEN	490	515
ORANGE	546	575
RED	593	618

Limitations:
This product is provided for Research Use Only (RUO) and is not for use in diagnostic procedures. Suitability for specific applications may vary and it is the responsibility of the end user to determine the appropriate application for its use.

Precautions:
1. This product contains formamide and fluorescent dyes that may be hazardous to your health. The SDS is available upon request and is located at <http://biocare.net>.
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water (4).

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Precautions Cont'd:

Health Hazard Irritant Corrosive (to skin)

Technical Support:

Contact Biocare's Technical Support at 1-800-542-2002 for questions regarding this product.

References:

1. Soda M., et al. Identification of the transforming EML4-ALK fusion gene in non-small-cell lung cancer. 2007. Nature 448:561-566.
2. Inamura K., et al. EML4-ALK fusion is linked to histological characteristics in a subset of lung cancers. 2008. J Thorac Oncol 3:13-17.
3. Shaw AT., et al. Clinical features and outcome of patients with non-small-cell lung cancer harboring EML4-ALK. 2009. J Clin Oncol 27:4247-4253.
4. Sasaki T., et al. The biology and treatment of EML4-ALK non-small cell lung cancer. 2010. Eur J Cancer 46:1773-1780.
5. Shaw AT., et al. Effect of crizotinib on overall survival in patients with advanced non-small-cell lung cancer harbouring ALK gene rearrangement: a retrospective analysis. 2011. The Lancet Oncol 12:1004-1012.
6. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from occupationally acquired infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.