DATA SHEET

ALK FISH DNA Probe, Split Signal

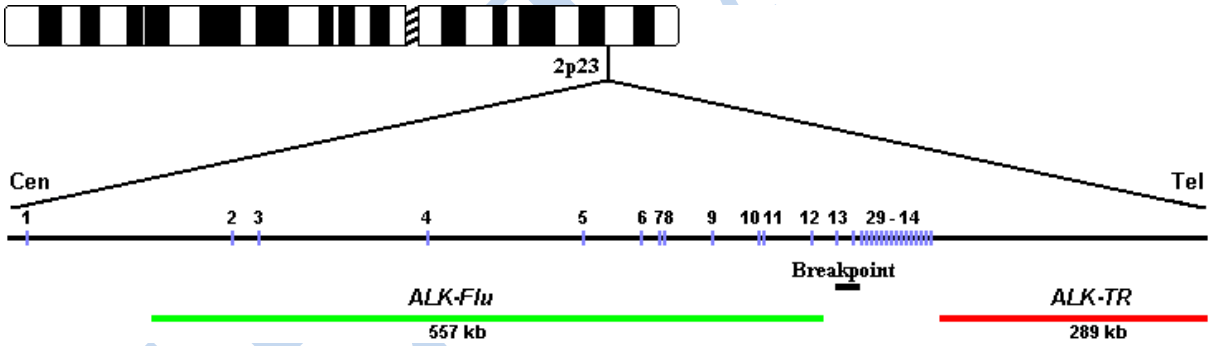
Code Y5417

Recommended use

ALK FISH DNA Probe, Split Signal, is recommended for the detection of translocations involving the *ALK* locus at chromosome 2p23 by fluorescence in situ hybridization (FISH). When the probe is used on cytology specimens the Cytology FISH Accessory Kit, Code K5499, is recommended. If the probe is used on histology specimens the Histology FISH Accessory Kit, Code K5599, is recommended. Both kits contain all key reagents, except for the probe, necessary to perform 20 FISH assays. It is recommended to denature at 82 °C for 5 minutes and hybridize at 45 °C in a humidified chamber for 14-20 hours, as decribed in the enclosed working procedure with the selected accessory kit.

Introduction

The human *ALK* (anaplastic lymphoma kinase) gene at chromosome 2 band p23 (1) consists of 29 exons and spans a region of ~729 kb. The *ALK* gene encodes a protein containing an extracellular domain, a transmembrane domain, a tyrosine kinase domain, and a C-terminal intracytoplasmic domain (2). The two DNA probes within *ALK*
FISH DNA Probe, Split Signal, are designed to hybridize upstream and downstream of the breakpoint cluster region. Co-localization of the probes results in a red/green signal, whereas translocation events in the breakpoint cluster region will split one signal in separate green (fluorescein) and red (Texas Red) signals.



Target (red)

The Texas Red-labeled DNA probe (*ALK-TR*) binds to a 289 kb segment telomeric to the *ALK* breakpoint cluster region on chromosome 2p23.

Target (green)

The fluorescein-labeled DNA probe (ALK-Flu) binds to a 557 kb segment centromeric to the ALK breakpoint cluster region on chromosome 2p23.

Probe gap

The gap between ALK-TR and ALK-Flu is 104 kb.

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Reagent provided

ALK FISH DNA Probe, Split Signal, is a mixture of two fluorochrome-labeled DNA probes and unlabeled PNA blocking probes. The DNA probes in the mixture consist of a fluorescein-labeled probe (*ALK-Upstream*) and a Texas Red-labeled probe (*ALK-Downstream*).

The reagent is provided in liquid form in hybridization solution containing 45% formamide, 10% dextran sulphate, 300 mmol/L NaCl, 5 mmol/L phosphate, and blocking agent.

Specificity

99.8%. Defined as the mean of 6 independent countings of 1050 cells from normal peripheral blood.

Precautions

1. The device is not intended for clinical use including diagnosis, prognosis, and monitoring af a disease state, and it must not be used in conjunction with patient records or treatment.

2. The reagent contains 45% formamide and is labeled:
Toxic.
R61 May cause harm to the unborn child.
S45 In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
S53 Avoid exposure – obtain special instructions before use.
S60 This material and/or its container must be disposed of as hazardous waste.
As a main rule, persons under 18 years of age are not allowed to work with this product. Users must be carefully instructed in the proper working procedure, the dangerous properties of the product and the necessary safety instructions. Please refer to the Material Safety Data Sheet (MSDS) for additional information.

Storage

Store in the dark at 2-8 °C. Do not use after expiration date stamped on vial. There are no obvious signs to indicate instability of this product. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the product is suspected, contact Dako Technical Services.

References

1. Morris SW, Kirstein MN, Valentine MB, Dittmer KG, Shapiro DN, Saltman DL, et al. Fusion of a kinase gene, ALK, to a nucleolar protein gene, NPM, in non-Hodgkin's lymphoma. Science 1994;263:1281-1284.
2. Iwahara T, Fujimoto J, Wen D, Cupples R, Bucay N, Arakawa T, et al. Molecular characterization of ALK, a receptor tyrosine kinase expressed specifically in the nervous system. Oncogene. 1997;14:439-49.