FlexISH®



Background

コスモ・バー

The FlexISH[®] ALK/ROS1 DistinguISH[™] Probe is designed to detect rearrangements involving the chromosomal region 2p23.1-p23.2 and 6q22.1 harboring the ALK (anaplastic lymphoma receptor tyrosine kinase, a.k.a. CD246) and ROS1 (c-ros oncogene 1) gene, respectively. Using this probe, it is possible to simultaneously detect ALK and ROS1 rearrangements and, additionally, to discriminate between possible aberrations affecting these chromosomal regions. Both, the ALK as well as the ROS1 gene, encode for transmembrane receptor tyrosine kinases. Rearrangements affecting the ALK or the ROS1 gene locus are frequently found in non-small cell lung cancer

(NSCLC). The most frequent ALK rearrangement in NSCLC is the inversion [inv(2)(p21p23)] affecting the genes ALK and EML4, both located on chromosome 2. The ROS1 gene is evolutionary closely related to the ALK family which forms part of the scientific basis of using inhibitors of ALK as inhibitors of ROS1. ALK and ROS1 positive NSCLC patients benefit from a tyrosine kinase targeted therapy, like, e.g., crizotinib.

References

Birchmaier C, et al. (1987) Proc Natl Acad Sci 84: 9270-4. Bos M, et al. (2013) Lung Cancer 81: 142-3. Sasaki T, et al. (2010) Eur J Cancer 46: 1773-80. Shaw AT, et al. (2014) N Engl J Med 371: 1963-71.



ALK Probe map (not to scale).

Probe Description

The FlexISH® ALK/ROS1 DistinguISH™ Probe is a mixture of five direct labeled probes hybridizing to the 2p23.1-p23.2 and 6q22.1-q22.2 bands. The orange fluorochrome direct labeled probe fractions hybridize distal to the ALK and ROS1 breakpoint regions, the green direct labeled probe fractions hybridize proximal to the ALK and ROS1 breakpoint regions. The blue fluorochrome direct labeled probe hybridizes distal and proximal to the ROS1 breakpoint region.

Results

In an interphase nucleus without ALK or ROS1 rearrangements, two ALK specific green/orange fusion signals and two ROS1 specific green/orange/blue fusion signals are expected. An ALK rearrangement is indicated by one separate orange signal and/or one separate green signal, both not co-localizing with blue signals. A ROS1 rearrangement is indicated by one separate green signal, and/or one separate orange signal both co-localizing with blue signals.

Molecular diagnostics simplified



Ideograms of chromosomes 2 (left) and 6 (right) indicating the hybridization locations.





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H3122 cell line which shows two green/orange/blue fusion signals and one orange/green fusion signal. An ALK rearrangement is indicated by one separate orange and one separate green signal, both not co-localizing with blue signals.



HCC78 cell line which shows two green/orange fusion signals and one green/orange/blue fusion signal. ROS1 rearrangement is indicated by one separate orange and one separate green signal, both co-localizing with blue signals.

Prod. No.	Product	Label	Tests* (Volume)	١
Z-2203-50	F/exISH ALK/ROS1 DistinguISH™ Probe C€ IVD	•/•/•	5 (50 µl)	
Z-2203-200	F/exISH ALK/ROS1 DistinguISH™ Probe C€ IVD	•/•/•	20 (200 µl)	
Related Produ	icts			
Z-2182-5	FlexISH-Tissue Implementation Kit C E IVD Incl. Heat Pretreatment Solution Citric, 150 ml; Pepsin Solution, 1 ml; 5x FlexISH Wash Buffer, 150 ml; DAPI/DuraTect-Solution, 0.2 ml		5	
Z-2182-20	F/exISH-Tissue Implementation Kit C C IVD		20	ļ
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* Using 10 µl probe solution per test. CE IVD only available in certain countries. All other countries research use only! Please contact your local dealer for more info<u>rmatio</u>

