

# FlexISH® ALK/ROS1 DistinguISH™ Probe

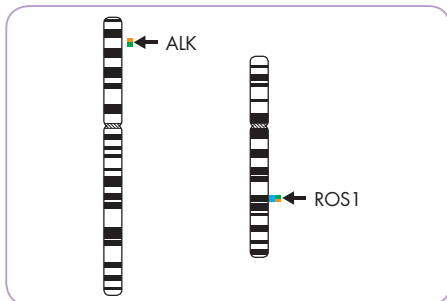


## Background

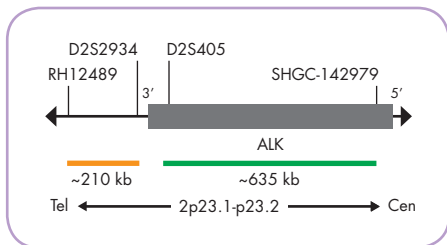
The FlexISH® ALK/ROS1 DistinguISH™ Probe (PL161) is intended to be used for the qualitative detection of translocations involving the human ALK gene at 2p23.1-p23.2 and the human ROS1 gene at 6q22.1 in formalin-fixed, paraffin-embedded specimens, such as non-small cell lung cancer (NSCLC), by fluorescence *in situ* hybridization (FISH). The probe is intended to be used in combination with the FlexISH®-Tissue Implementation Kit (Prod. No. Z-2182-5/-20).

The product is intended for professional use only. All tests using the product should be performed in a certified, licensed anatomic pathology laboratory under the supervision of a pathologist/human geneticist by qualified personnel.

The probe is intended to be used as an aid to the differential diagnosis of NSCLC and therapeutic measures should not be initiated based on the test result alone.



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

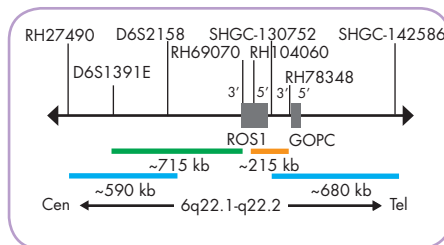


ALK Probe map (not to scale).

## Probe Description

The FlexISH® ALK/ROS1 DistinguISH™ Probe is composed of:

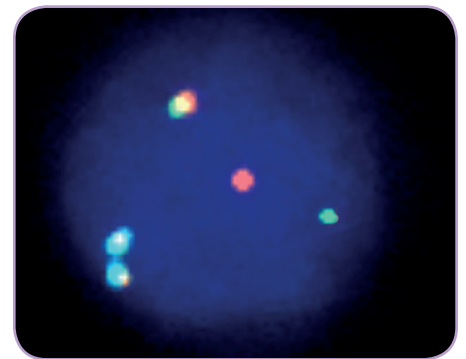
- ZyGreen (excitation 503 nm/emission 528 nm) labeled polynucleotides (~10.0 ng/µl), which target sequences mapping in 2p23.1-p23.2\*\* (chr2:29,460,144-30,095,822) proximal to the ALK breakpoint region and in 6q22.1\*\* (chr6:116,912,298-117,627,255) proximal to the ROS1 breakpoint region.
- ZyOrange (excitation 547 nm/emission 572 nm) labeled polynucleotides (~2.5 ng/µl), which target sequences mapping in 2p23.2\*\* (chr2:29,174,204-29,383,335) distal to the ALK breakpoint region and in 6q22.1\*\* (chr6:117,659,135-117,871,701) distal to the ROS1 breakpoint region.
- ZyBlue (excitation 418 nm/emission 467 nm) labeled polynucleotides, (~70.0 ng/µl), which target sequences mapping in 6q22.1\*\* (chr6:116,671,642-117,260,761) proximal to the ROS1 breakpoint region co-localizing with the green-labeled ROS1 polynucleotides and in 6q22.1-q22.2\*\* (chr6:117,765,211-118,444,005) distal to the ROS1 breakpoint region co-localizing with the orange-labeled ROS1 polynucleotides.
- Formamide based hybridization buffer



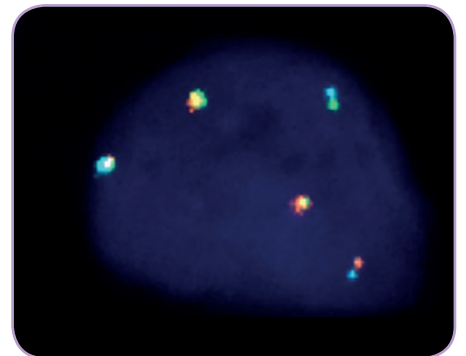
ROS1 Probe map (not to scale).

## 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.



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.



Paraffin-embedded 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)
Z-2203-50	FlexISH ALK/ROS1 DistinguISH Probe CE IVD	●/●/●	5 (50 µl)
Z-2203-200	FlexISH ALK/ROS1 DistinguISH Probe CE IVD	●/●/●	20 (200 µl)
Related Products			
Z-2182-5	FlexISH-Tissue Implementation Kit CE 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	FlexISH-Tissue Implementation Kit CE IVD Incl. Heat Pretreatment Solution Citric, 500 ml; Pepsin Solution, 4 ml; 5x FlexISH Wash Buffer, 500 ml; DAPI/DuraTect-Solution, 0.8 ml		20

\* Using 10 µl probe solution per test. IVD labeled products are only available in certain countries. All other countries research use only! Please contact your local dealer for more information.

\*\*According to Human Genome Assembly GRCh37/hg19