

Fluorescence in-situ Hybridization (FISH)

ALK1 Break Apart Rearrangement Assay

Specimen : Formalin fixed paraffin embedded tissue block.

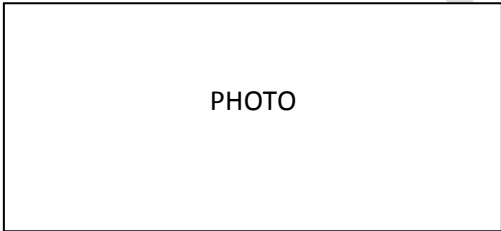
Block No : Free text

Clinical Indication : Free text.

Result : Free text.

Interpretation :Specimen is positive/negative for ALK1 break apart rearrangement.

Interphase nuclei analyzed	Normal nuclei 2 YellowSignals	Abnormal nuclei 1 Orange 1 Green 1 Yellow signals
100	100	00



Method: FISH (Fluorescence in situ hybridization) on formalin fixed paraffin embedded tumor tissue.

Probe: LSI ALK1 (2p23) Spectrum Orange Spectrum Green probe.

Cut off :Sample is considered negative if <10% cells are positive
Sample is considered positive if >50% cells are positive
Sample is considered equivocal if <10 to 50% cells are positive

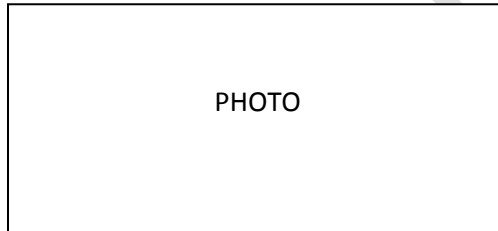
Comments:Approximately 3-5% of Non-Small Cell Lung Carcinomas (NSCLC) have a rearrangement of the ALK gene, resulting in fusion between ALK and another gene, ALK activation, impaired apoptosis, and abnormal cell proliferation. Patients with such tumors have been shown to respond to the ALK kinase inhibitor XALKORI® (Crizotinib). ALK rearrangement testing by FISH along with EGFR molecular testing are recommended for recurrent or metastatic cases with histological subtypes of Adenocarcinoma, Large cell carcinoma, or NSCLC NOS (not otherwise specified), and Squamous cell carcinoma in non-smokers or when biopsy specimens are small. FISH technique is the gold standard for detecting ALK-1 gene rearrangements.

Fluorescence in-situ Hybridization (FISH)

ROS1 Break Apart Rearrangement Assay

Specimen : Formalin fixed paraffin embedded tissue block.
Block No : Free text
Clinical Indication : Free text.
Result : Free text.
Interpretation :Specimen is positive/negative for ROS1 break apart rearrangement.

Interphase nuclei analyzed	Normal nuclei 2 YellowSignals	Abnormal nuclei 1 Orange 1 Green 1 Yellow signals
100	100	00



Method: FISH (Fluorescence in situ hybridization) on formalin fixed paraffin embedded tumor tissue.

Probe: LSI ROS1 (6q21) Spectrum Orange Spectrum Green probe.

Cut off :Sample is considered negative if <10% cells are positive
Sample is considered positive if >50% cells are positive
Sample is considered equivocal if <10 to 50% cells are positive

Comments:ROS1 rearrangements have been exclusively detected in adenocarcinoma of the lung and are thought to define a molecular subset of NSCLC with distinct clinical characteristics that are similar to those observed in patients with ALK rearranged NSCLC. Fluorescence in situ Hybridization might be a helpful tool for the identification of patients likely to respond to ROS1 kinase targeting therapies.

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