ROS1 BY FISH
Non-Small Cell Lung Cancer
April 2017

CLINICAL USE

The ROS1 SureFISH Break Apart Probe is a qualitative test to detect rearrangements involving the ROS1 gene in non-small cell lung cancer tissue specimens via Fluorescence in situ hybridization (FISH). ROS1 FISH is intended to aid in identifying those patients eligible for treatment with XALKORI (Crizotinib). The ROS1 FISH test can be ordered in conjunction with EGFR mutation testing by PCR and ALK FISH testing as a Lung Cancer Panel.

CLINICAL BACKGROUND

Rearrangements of the ROS1 gene have been identified in approximately 1-2% of NSCLC tumors. Patients with ROS1 rearrangements tend to be young never-smokers with adenocarcinoma. The ROS1 gene can fuse with other genes to form an abnormal, constitutively active tyrosine kinase receptor. This “fusion protein” results in continuous cell proliferation signaling. ROS1 rearrangements rarely present simultaneously with EGFR, KRAS or ALK alterations. Crizotinib, a targeted tyrosine kinase receptor inhibitor, has shown inhibitory growth effects on ROS1-rearranged NSCLC. In recent clinical studies, patients with advanced NSCLC harboring ROS1 rearrangements derived great benefit from crizotinib treatment. However, due to the low frequency of ROS1 fusion in lung cancers, efficient determination of ROS1 status in NSCLC patients is critical for directing patient care.

SPECIMEN REQUIREMENTS:

Specimen:	FFPET – formalin-fixed, paraffin-embedded NSCLC tissue
Stability:	Room temperature (15-30°C) indefinitely; 5 micron sections mounted on slides may be stored at 15-30°C for up to 60 days.
Cause for Rejection:	Absence of tumor cells
Method:	Fluorescence in situ hybridization (FISH).
Turnaround Time:	Testing is batched once a week.
CPT code*:	88377
SOFT code:	ROS1 (This code may be different in your EMR)

***CPT codes provided are for informational purposes only. Questions regarding coding should be directed to the payor.**