

ROS1 gene rearrangement by FISH in formalin-fixed paraffin embedded (FFPE) tissue



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Laboratory Medicine

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The information contained in this flyer is intended for healthcare professionals.

INTENT OF USE:

This test is based on the **Fluorescent In-situ Hybridization** technique using a specialized **ROS1(6q22) Gene Fusion Probe Kit** to detect ROS1 gene rearrangement and is useful for identifying tumors that may be sensitive to targeted therapy.

INTRODUCTION:

ROS1 rearrangements occur in ~1–2% of Non-Small Cell Lung carcinoma (NSCLC), typically in younger, non-smoking patients with adenocarcinoma. A positive result identifies patients eligible for ROS1-targeted TKIs (e.g., crizotinib, entrectinib, lorlatinib treatment), which yield high response rates. The ROS1 gene, located on chromosome 6q22, encodes a receptor tyrosine kinase. Chromosomal rearrangements involving the fusion of the 3' region of ROS1 with the 5' region of diverse partner genes were initially described in non-small cell lung carcinoma (NSCLC). Since then, ROS1 fusions have been reported in a spectrum of neoplasms, including inflammatory myofibroblastic tumors and cutaneous melanocytic tumors, among others.

From a clinical perspective, evidence indicates that tumors harboring ROS1 fusions are potentially sensitive to targeted therapy, underscoring their relevance as a predictive biomarker.

IMPORTANT NOTE:

In non-small cell lung carcinoma (NSCLC), ROS1 rearrangements are most frequently seen in adenocarcinomas, often with solid, acinar, or papillary growth patterns and signet-ring cell features.

The identification of a ROS1 fusion has important predictive and therapeutic implications, as such tumors may respond to ROS1-targeted tyrosine kinase.

PRINCIPLE:

Fluorescent in situ hybridization (FISH)

SPECIMEN TYPE:

Formalin-fixed paraffin-embedded (FFPE) NSCLC specimen.

ADDITIONAL INFORMATION :

ROS1 fusions are enriched in younger patients, never-smokers or light smokers, and those with advanced-stage lung adenocarcinoma.

Positive ROS1 results provide a predictive biomarker for eligibility for TKI therapy, which can lead to significant and durable clinical responses.

Negative results do not exclude other actionable fusions (e.g., ALK, RET, NTRK, MET), for which comprehensive molecular profiling may be considered.

CHARGES:

PKR 30,000/

*Revisions may apply

SCHEDULE:

Test is performed every Thursday; report will be issued after 7 days .

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