TEST ID: FALKC

ALK ON CYTOLOGY SPECIMENS, FISH

USEFUL FOR

Detection of rearrangements involving the ALK gene region at 2p23 in patients with non-small cell lung carcinoma who may benefit from treatment with the ALK inhibitor drugs, like Xalkori (Crizotinib), on previously stained routine cytology slides.

CLINICAL INFORMATION

Lung cancer is the leading cause of cancer death in the United States. Non-small cell lung carcinoma (NSCLC) accounts for 75% to 80% of all lung cancers with an overall 5-year survival rate of 10% to 15%. Standard chemotherapy regimens have had marginal success in improving clinical outcomes.

Rearrangements of the anaplastic lymphoma receptor tyrosine kinase (ALK) locus are found in a small subset of lung carcinomas and the identification of ALK-driven lung cancer guides important therapeutic management of these tumors. Rearrangement (translocation) of the ALK gene with a fusion partner gene, most commonly echinoderm microtubule-associated protein-like 4 (EML4), results in a constitutively active fusion gene. Lung cancers harboring ALK rearrangements are highly sensitive to ALK inhibitor drugs, which work by blocking certain kinases including those produced by the abnormal ALK fusion gene. The FDA has approved the use of Xalkori (Crizotinib), an ALK inhibitor drug, for NSCLC patients with tumors exhibiting ALK rearrangements. The FDA-approved companion diagnostic assay for the detection of the ALK gene rearrangements is a FISH test that utilizes the Vysis ALK break apart FISH probe kit and is approved for formalin-fixed, paraffin-embedded (FFPE) material only. Unfortunately, not all NSCLC patients have sufficient FFPE material for ALK testing.

INTERPRETATION

An interpretive report will be provided.

SUPPORTIVE DATA

Verification studies were performed on 25 samples and demonstrated acceptable concordant results between the FDA method (concurrent formalin-fixed paraffin-embedded tissue) and a laboratory-developed protocol (cytology slide).

REFERENCE VALUES

An interpretative report will be provided.

ANALYTIC TIME

5 days
CLINICAL REFERENCE


