



Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



ALK Mutation Analysis

Alternative Name

ALK Mutation

Methodology

Molecular

Test Description

Bi-directional Sanger sequencing of ALK is performed using PCR primers designed to target hotspot mutations in exons 23 and 25.

Clinical Significance

ALK gene translocations are a well-known cause of gene deregulation and target of ALK inhibitors in non-small cell lung carcinoma (NSCLC). However, point mutations in the ALK tyrosine kinase domain, such as those detected by this test, are reported in patients who develop resistance to this therapy. Mutation analysis can help predict sensitivity or resistance to first and second generation inhibitors such as crizotinib, alectinib, and ceritinib. Reported mutations include F1174V, F1174L, L1196M, and G1202R.

Note: This test is not designed to detect ALK fusions. To test for ALK rearrangement/fusions, either [ALK for NSCLC FISH](#) or [Lung NGS Fusion Panel \(Complete\)](#) are suggested.

Specimen Requirements

- **FFPE tissue:** Paraffin block is preferred. Alternatively, send 1 H&E slide plus 5-10 unstained slides cut at 5 or more microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

Storage & Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen. All slides can be packed at room temperature.

CPT Code(s)*

81479

New York Approved

No

Level of Service

Global

Turnaround Time

7-10 days

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the payor being billed.

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