



Test Definition: ALKLC

Anaplastic Lymphoma Kinase for Lung Cancer,
Immunohistochemistry

Overview

Useful For

Identification of anaplastic lymphoma kinase (ALK) expression

Prediction of tumor response to targeted therapy of non-small cell lung carcinomas.

Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---------|----------------|----------------------|------------------|
| IHPCA | IHC Additional | No | No |
| IHPCI | IHC Initial | No | No |

Testing Algorithm

For the initial immunohistochemistry (IHC) stain performed, the appropriate bill-only test ID will be added and charged (IHPCI). For each additional IHC stain performed, an additional bill-only test ID will be added and charged (IHPCA).

Method Name

Immunohistochemistry (IHC)

NY State Available

Yes

Specimen

Specimen Type

Special

Shipping Instructions

Attach the green "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

Necessary Information

A pathology/diagnostic report and a brief history, including primary site of neoplasm, are required.

Specimen Required

Specimen Type: Tissue

Supplies: Pathology Packaging Kit (T554)

Submit:

Formalin-fixed, paraffin-embedded tissue block

OR

3 Unstained glass, "positively charged" slides with 4-microns formalin-fixed, paraffin-embedded tissue

Additional Information: One slide will be stained with hematoxylin and eosin and returned.

Forms

If not ordering electronically, complete, print, and send a [Immunohistochemical \(IHC\)/In Situ Hybridization \(ISH\) Stains Request](#) (T763) with the specimen.

Reject Due To

| | |
|---|--------|
| Wet/frozen tissue | Reject |
| Decalcified paraffin embedded tissue | Reject |
| Cytology smears | Reject |
| Nonformalin fixed tissue including alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER fixatives or zinc formalin | Reject |
| Nonparaffin embedded tissue | Reject |
| Noncharged slides | Reject |
| ProbeOn slides | Reject |
| Snowcoat slides | Reject |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|---------------------|------|-------------------|
| Special | Ambient (preferred) | | |
| | Refrigerated | | |

Clinical & Interpretive

Clinical Information

A subset of lung cancers, specifically adenocarcinomas, harbor anaplastic lymphoma kinase (*ALK*) rearrangements. Expression of *ALK* in tumor cells can be used as a surrogate marker for *ALK* rearrangement. The presence of *ALK* rearrangement (*ALK* protein expression) is a predictive biomarker for response to *ALK* tyrosine kinase inhibitors.

Interpretation

This test, when not accompanied by a pathology consultation request, will be answered as either positive or negative. If additional interpretation or analysis is needed, request PATHC / Pathology Consultation along with this test.

Cautions

This test has been validated for non-decalcified paraffin-embedded tissue specimens fixed in 10% neutral buffered formalin at Mayo Clinic in Rochester, Minnesota. Specimens are recommended to be placed in formalin within 1 hour of acquisition and fixed between 6 hours and 48 hours. This assay has not been validated on tissue or cellblocks subjected to alternative fixatives or decalcification.

Age of a cut paraffin section can affect immunoreactivity. Stability thresholds vary widely among published literature and are antigen dependent. Best practice is for paraffin sections to be cut within 6 weeks.

The charge of glass slides can be affected by environmental factors and subsequently may alter slide staining. Sending unsuitable glass slides can result in inconsistent staining due to poor slide surface chemistry.

Best practices for storage of positively charged slides:

- Minimize time slides are stored after being unpackaged
- Limit exposure to high humidity and heat
- Minimize exposure to plastics

Clinical Reference

1. Hutarew G, Hauser-Kronberger C, Strasser F, Llenos IC, Dietze O. Immunohistochemistry as a screening tool for *ALK* rearrangement in NSCLC: evaluation of five different *ALK* antibody clones and *ALK* FISH. *Histopathology*. 2014;65(3):398-407
2. Stein H, Foss HD, Durkop H, et al. CD30(+) anaplastic large cell lymphoma: a review of its histopathologic, genetic, and clinical features. *Blood*. 2000;96(12):3681-3695
3. Yi ES, Boland JM, Maleszewski JJ, et al. Correlation of IHC and FISH for *ALK* gene rearrangement in non-small cell lung carcinoma: IHC score algorithm for FISH. *J Thorac Oncol*. 2011;6(3):459-465

Performance

Method Description

Immunohistochemistry on sections of paraffin-embedded tissue.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

5 to 7 days

Specimen Retention Time

Until reported

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88342-Primary

88341-If additional IHC

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|-------------------------|--------------------|
| ALKLC | ALK for Lung Cancer IHC | 47303-3 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|------------------------------------|---------------------|
| 615714 | Interpretation | 59465-5 |
| 615715 | Participated in the Interpretation | No LOINC Needed |
| 615716 | Report electronically signed by | 19139-5 |
| 615717 | Material Received | 81178-6 |
| 615718 | Disclaimer | 62364-5 |
| 615719 | Case Number | 80398-1 |