MAYO CLINIC LABORATORIES

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:

1. One slide will be stained with hematoxylin and eosin and returned.

2. Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

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
Broken or cracked unstained slides	Reject

Broken or cracked stained slides that cannot be repaired	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

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

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