

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) included in the kit to the outside of the transport container.

Necessary Information

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

Specimen Required

**Supplies:** Pathology Packaging Kit (T554)

**Specimen Type:** 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
Cytology smears	Reject
Nonformalin fixed tissue	Reject
Nonparaffin embedded tissue	Reject
Noncharged slides	Reject
ProbeOn 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. Recommended fixation time is between 6 hours and 48 hours. This assay has not been validated on tissues subjected to the decalcification process or use of alternative fixatives for bone and bone marrow specimens or cell blocks.

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