

## Overview

### Useful For

Identification of ALK overexpression

### Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
IHTOI	IHC Initial, Tech Only	No	No
IHTOA	IHC Additional, Tech Only	No	No

## Testing Algorithm

For the initial technical component only immunohistochemical (IHC) stain performed, the appropriate bill-only test ID will be reflexed and charged (IHTOI). For each additional technical component only IHC stain performed, an additional bill-only test ID will be reflexed and charged (IHTOA).

### Method Name

Immunohistochemistry

### NY State Available

Yes

## Specimen

### Specimen Type

TECHONLY

### Advisory Information

This test includes only technical performance of the stain (no pathologist interpretation is performed). If diagnostic consultation by a pathologist is required order PATHC / Pathology Consultation.

### Shipping Instructions

Attach the green pathology address label and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

### Specimen Required

**Supplies:** Immunostain Technical Only Envelope (T693)

**Specimen Type:** Tissue

**Preferred:** 2 Unstained positively charged glass slide (25- x 75- x 1-mm) per test ordered; sections 4-microns thick.

**Acceptable:** Formalin-fixed, paraffin-embedded (FFPE) tissue block

### Digital Image Access

1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can

be accessed through this website: [www.mayocliniclabs.com/test-info/ihc/index.html](http://www.mayocliniclabs.com/test-info/ihc/index.html)

2. Clients ordering stains using a manual requisition form will not have access to digital images.
3. Clients wishing to access digital images must place the order for IHC stains electronically. Information regarding digital imaging can be accessed through this website: [www.mayocliniclabs.com/test-info/ihc/faq.html](http://www.mayocliniclabs.com/test-info/ihc/faq.html)

**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**

Tissue/Other	Wet/frozen tissue Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides
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**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
TECHONLY	Ambient (preferred)		
	Refrigerated		

**Clinical and Interpretive**

**Clinical Information**

A subset of anaplastic large-cell lymphomas show overexpression of anaplastic lymphoma kinase (ALK-1) protein, resulting from a translocation involving the *ALK1* gene. The abnormal ALK-1 expression can be in a nuclear and cytoplasmic distribution. Overexpression of ALK-1 protein is also useful in the diagnosis of lung adenocarcinoma and inflammatory myofibroblastic tumor. In normal tissue ALK-1 is negative.

**Interpretation**

The positive and negative controls are verified as showing appropriate immunoreactivity. If a control tissue is not included on the slide, a scanned image of the relevant quality control tissue is available upon request. Contact 855-516-8404.

Interpretation of this test should be performed in the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

**Cautions**

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 fresh.

**Clinical Reference**

1. Hutarew G, Hauser-Kronberger C, Strasser F, et al: Immunohistochemistry as a screening tool for ALK rearrangement in NSCLC: evaluation of five different ALK antibody clones and ALK FISH. *Histopathology* 2014;65:398-407

2. Stein H, Foss H, 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.(Cartun RW, Taylor CR, Dabbs DJ: Techniques of immunohistochemistry: Principles, pitfalls, and standardization. In: Dabbs DJ, ed. Diagnostic Immunohistochemistry. 5th ed. Elsevier; 2019:1-46)

### PDF Report

No

### Day(s) and Time(s) Test Performed

Monday through Friday

### Analytic Time

1 day

### Maximum Laboratory Time

3 days

### Specimen Retention Time

Until staining is complete.

### Performing Laboratory Location

Rochester

## Fees and 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 Regional Manager. For assistance, contact [Customer Service](#).

### Test Classification

This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

### CPT Code Information

88342-TC, primary

88341-TC, if additional IHC

### LOINC® Information



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Test ID	Test Order Name	Order LOINC Value
ALK	ALK IHC, Tech Only	Order only;no result

Result ID	Test Result Name	Result LOINC Value
70668	ALK IHC, Tech only	Bill only; no result