

Test Definition: ALKD5

Anaplastic Lymphoma Kinase (ALK[D5F3])
Immunostain, Technical Component Only

Overview

Useful For

Identification of anaplastic lymphoma kinase overexpression

Diagnosis of lung adenocarcinoma and inflammatory myofibroblastic tumor

Reflex Tests

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

NY State Available

Yes

Specimen

Specimen Type

TECHONLY

Ordering Guidance

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

Specimen Type: Tissue

Supplies: Immunostain Technical Only Envelope (T693)

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Container/Tube: Immunostain Technical Only Envelope

Preferred:

Formalin-fixed, paraffin-embedded tissue block

OR

2 Unstained, positively charged glass slides (25- x 75- x 1-mm) per test ordered; sections 4-microns thick

Acceptable: None

Digital Image Access

- 1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: <https://news.mayocliniclabs.com/ihc-stains/>
- 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: <https://news.mayocliniclabs.com/ihc-stains/#FAQ>

Forms

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

Specimen Minimum Volume

See Specimen Required

Reject Due To

Wet/frozen tissue Cytology smears Nonformalin fixed tissue Nonparaffin embedded tissue Noncharged slides ProbeOn slides Snowcoat slides	Reject
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Specimen Stability Information

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

Clinical & Interpretive**Clinical Information**

A subset of anaplastic large-cell lymphomas shows 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 or 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

This test does not include pathologist interpretation, only technical performance of the stain. If interpretation is required, order PATHC / Pathology Consultation for a full diagnostic evaluation or second opinion of the case.

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, call 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 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;65:398-407
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
4. Magaki S, Hojat SA, Wei B, So A, Yong WH. An introduction to the performance of immunohistochemistry. *Methods Mol Biol*. 2019;1897:289-298. doi:10.1007/978-1-4939-8935-5_25

Performance

Method Description

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

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 days

Specimen Retention Time

Until staining is complete.

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-TC, primary
88341-TC, if additional IHC

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ALKD5	ALK(D5F3) IHC, Tech Only	No LOINC Needed

Result ID	Test Result Name	Result LOINC® Value
620967	ALK(D5F3) IHC, Tech Only	No LOINC Needed