

Overview

Useful For

Identification of anaplastic lymphoma kinase overexpression

Diagnosis of inflammatory myofibroblastic tumor and anaplastic large cell lymphoma

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 (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)

Test Definition: ALKOT

Anaplastic Lymphoma Kinase (ALK [OTI1A4])
Immunostain, Technical Component Only

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/pathology/digital-imaging/>
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/pathology/digital-imaging/#section3>

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 |
|---|--------|

Specimen Stability Information

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

Clinical & 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 or cytoplasmic distribution. Overexpression of ALK-1 protein can also be useful in the diagnosis of inflammatory myofibroblastic tumor and ALK-positive histiocytosis. In normal tissue, ALK-1 expression is primarily limited to neurons and ganglion cells. This clone, OTI1A4, is not validated for use in lung adenocarcinoma.

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 and documentation is retained at Mayo Clinic Rochester. 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. Preobrazhenskaya E, Iyevleva A, Suleymanova A, et al. Gene rearrangements in consecutive series of pediatric inflammatory myofibroblastic tumors. *Pediatr Blood Cancer*. 2020;67(5):e28220
2. Mansour B, Bonati M, Michalove K, et al. Epithelioid fibrous histiocytoma: three diagnostically challenging cases with novel ALK gene fusions, unusual storiform growth pattern, and a prominent spindled morphology. *Virchows Archiv*. 2022;481(5):751-757
3. He J, Zhao X, Huang C, et al. Double amplifications of CDK4 and MDM2 in a gastric inflammatory myofibroblastic tumor mimicking cancer with local invasion of the spleen and diaphragm. *Cancer Biology & Therapy*. 2018;19:11:967-972
4. Kemps PG, Picarsic J, Durham BH, et al. ALK-positive histiocytosis: a new clinicopathologic spectrum highlighting neurologic involvement and responses to ALK inhibition. *Blood*. 2022;139(2):256-280

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

Rochester

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 |
|---------|----------------------------|--------------------|
| ALKOT | ALK(OTI1A4) IHC, Tech Only | No LOINC Needed |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|----------------------------|---------------------|
| 620406 | ALK(OTI1A4) IHC, Tech Only | No LOINC Needed |