

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

#### Overview

#### **Useful For**

Identification of anaplastic lymphoma kinase expression

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 "Attention Pathology" address label (T498) 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

**Submit:** 

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

## **Digital Image Access**

- 1. Information on accessing digital images of immunohistochemical (IHC) stains and the manual requisition form can be accessed through this website: <a href="https://news.mayocliniclabs.com/pathology/digital-imaging/">https://news.mayocliniclabs.com/pathology/digital-imaging/</a>
- 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: <a href="https://news.mayocliniclabs.com/pathology/digital-imaging/#section3">https://news.mayocliniclabs.com/pathology/digital-imaging/#section3</a>

#### **Forms**

If not ordering electronically, complete, print, and send a <u>Immunohistochemical (IHC)/In Situ Hybridization (ISH) Stains</u>
Request (T763) with the specimen.

# **Specimen Minimum Volume**

See Specimen Required

#### Reject Due To

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

# **Specimen Stability Information**

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



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## Clinical & Interpretive

#### **Clinical Information**

A subset of anaplastic large-cell lymphomas show expression of anaplastic lymphoma kinase (ALK) protein, resulting from a translocation involving the *ALK1* gene. The abnormal ALK expression can be in a nuclear or cytoplasmic distribution. Expression of ALK 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 as predictive biomarker in non-small cell carcinomas of the lung.

# 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.

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**



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# **Method Description**

Immunohistochemistry on sections of paraffin-embedded tissue.(Unpublished Mayo method)

#### **PDF Report**

Nο

### 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 <u>Test Prices</u> for detailed fee information.
- Clients without access to Test Prices can contact <u>Customer Service</u> 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact <u>Customer Service</u>.

#### **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	