

Melanoma-associated antigen-A4 (MAGE-A4), Semi-Quantitative Immunohistochemistry, Manual

#### Overview

#### **Useful For**

Determining expression of melanoma-associated antigen-A4 (MAGE-A4) in synovial sarcoma and other neoplasms

As an aid in screening patients who may be eligible for TECELRA (afamitresgene autoleucel) therapy

#### **Method Name**

Immunohistochemistry (IHC)

# **NY State Available**

Yes

# **Specimen**

# **Specimen Type**

Special

# **Shipping Instructions**

Attach the green "Attention Pathology" address label (T498) to the outside of the transport container before putting into the courier mailer.

# **Necessary Information**

A pathology/diagnostic report and a brief history are required.

## Specimen Required

Specimen Type: Tissue

Supplies: Pathology Packaging Kit (T554)

Submit:

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.

## **Specimen Minimum Volume**

See Specimen Required

# Reject Due To



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Decalcified	Reject
paraffin	
embedded	
tissue	
Wet/frozen	Reject
tissue	
Cytology	Reject
smears	
Nonformalin	Reject
fixed tissue	
including	
alcohol-formali	
n-acetic acid	
(AFA), 95%	
ethanol,	
PREFER	
fixatives or	
Zinc formalin	
Nonparaffin	Reject
embedded	
tissue	
Noncharged	Reject
slides	
ProbeOn slides	Reject
Snowcoat	Reject
slides	

# **Specimen Stability Information**

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

# **Clinical & Interpretive**

## **Clinical Information**

Melanoma-associated antigen-A4 (MAGE-A4) is a cancer testis antigen (CTA). CTAs are targets for T-cell receptor immunotherapy. The MAGE-A4 immunohistochemical assay aids in identifying patients with synovial sarcoma and potentially other tumors for treatment with TECELRA (afamitresgene autoleucel), a MAGE-A4-directed genetically modified autologous T-cell immunotherapy.



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#### **Reference Values**

An interpretive report will be provided.

### Interpretation

Melanoma-associated antigen-A4 (MAGE-A4) in synovial sarcomas is determined positive when there is at least moderate to strong cytoplasmic and/or nuclear staining in greater than or equal to 75% of tumor cells.(1)

This result should be interpreted in the appropriate clinical context.

# **Cautions**

This test has been validated for nondecalcified paraffin-embedded tissue specimens fixed in 10% neutral-buffered formalin. Recommended fixation time is between 6 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

#### **Clinical Reference**

- 1. Instruction manual: MAGE-A4 IHC 1F9 pharmDx Interpretation Manual-Synovial Sarcoma. Agilent Technologies, Inc; 08/29/2024
- 2. Caballero O, Chen Y. Cancer/testis (CT) antigens Potential targets for immunotherapy. Cancer Science 2009;100(11):2014-2021
- 3. Hong D, Van Tine B, Biswas S, et al. Autologous T cell therapy for MAGE-A4+ solid cancers in HLA-A\*02+ patients a phase 1 trial. Nature Medicine 2023;29:104-114
- 4. Wang T, Navenot JM, Rafail S, et al. Identifying MAGE-A4-positive tumors for TCR T cell therapies in HLA-A\*02-eligible patients. Mol Ther Methods Clin Dev. 2024;32(2):101265. Published 2024 May 14. doi:10.1016/j.omtm.2024.101265

#### **Performance**

# **Method Description**

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

### PDF Report

No

## Day(s) Performed



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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 <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**

88360

## **LOINC®** Information

Test ID	Test Order Name	Order LOINC® Value
MAGE4	MAGE-A4, SemiQuant IHC, Manual	In Process

Result ID	Test Result Name	Result LOINC® Value
622998	Interpretation	59465-5
622999	Participated in the Interpretation	No LOINC Needed
623000	Report electronically signed by	19139-5
623001	Material Received	81178-6
623002	Disclaimer	62364-5
623003	Case Number	80398-1