Test Definition: MAGE4

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:

1. One slide will be stained with hematoxylin and eosin and returned.
2. Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

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

Decalcified paraffin embedded tissue	Reject
Wet/frozen tissue	Reject
Cytology smears	Reject
Nonformalin fixed tissue including alcohol-formalin-acetic acid (AFA), 95% ethanol, PREFER fixatives or zinc formalin	Reject
Nonparaffin embedded tissue	Reject
Noncharged, ProbeOn or Snowcoat slides	Reject
Broken or cracked unstained slides	Reject
Broken or cracked stained slides that cannot be repaired	Reject

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.

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 non-decalcified paraffin-embedded tissue specimens fixed in 10% neutral buffered formalin at Mayo Clinic in Rochester, Minnesota. Specimens are recommended to be placed in formalin within 1 hour of acquisition and fixed between 6 hours and 72 hours. This assay has not been validated on tissue or cellblocks subjected to alternative fixatives or decalcification.

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

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

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

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 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.

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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	111581-5

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