Test Definition: KM55

Galactose Deficient IgA1 (KM55) Immunostain, Technical Component Only

Overview

Useful For

Identification of Galactose deficient IgA1 by KM55, useful in the diagnosis of IgA nephropathy

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 provided**.

Technical component only stains **should not** be ordered with PATHC / Pathology Consultation. If ordered with PATHC, the technical component stains **will be canceled**. Any immunohistochemistry (IHC)/in situ hybridization (ISH) stain performed as a part of the PATHC will be performed at the reviewing pathologist's discretion at an additional charge.

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

Test Definition: KM55

Galactose Deficient IgA1 (KM55) Immunostain, Technical Component Only

Supplies: Immunostain Technical Only Envelope (T693)
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
Additional Information: 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.

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.

Reject Due To

Wet/frozen tissue	Reject
Cytology smears	Reject
Non-formalin fixed tissue	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	Reject

repaired	

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

KM55 antibody has been shown to identify galactose deficient IgA1 (Gd-IgA1), useful in the diagnosis of IgA nephropathy. Gd-IgA1 (KM55) is detected in the glomeruli of patients with IgA nephropathy and IgA vasculitis and may aid in distinguishing IgA nephropathy and IgA vasculitis from other glomerular diseases with IgA deposits detected by routine IgA staining.

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

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. Bu L, Ye B, Kouri AM, Kim Y. Diagnostic Utility of Galactose-Deficient Immunoglobulin A1 Immunostaining in the Differentiation of Lupus Nephritis and Immunoglobulin A Nephropathy. Glomerular Dis. 2021;1(1):34-39. Published 2021 Mar 10. doi:10.1159/000511056
2. Suzuki H, Yasutake J, Makita Y, et al. IgA nephropathy and IgA vasculitis with nephritis have a shared feature involving galactose-deficient IgA1-oriented pathogenesis. Kidney Int. 2018;93(3):700-705. doi:10.1016/j.kint.2017.10.019
3. Raj R, Sharma A, Barwad A, et al. KM55 in the Evaluation of IgA-Containing Glomerular Diseases. Glomerular Dis. 2021;2(2):59-74. Published 2021 Nov 2. doi:10.1159/000520640
4. Zhang K, Li Q, Zhang Y, et al. Clinical Significance of Galactose-Deficient IgA1 by KM55 in Patients with IgA Nephropathy. Kidney Blood Press Res. 2019;44(5):1196-1206. doi:10.1159/000502579

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 has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA

requirements.

CPT Code Information

88342-TC, Primary
88341-TC, If additional IHC

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
KM55	KM55 IHC, Tech Only	No LOINC Needed

Result ID	Test Result Name	Result LOINC® Value
621067	KM55 IHC, Tech Only	No LOINC Needed