Test Definition: CALRC

Calreticulin ex9mut Immunostain, Technical Component Only

Overview

Useful For

Identifying the presence of *CALR* exon 9 frameshift alterations in myeloproliferative neoplasms

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 pathology address label and the pink Immunostain Technical Only label included in the kit to the outside of the transport container.

Specimen Required

Supplies: Immunostain Technical Only Envelope (T693)

Specimen Type: Tissue
Container/Tube: Immunostain Technical Only Envelope
Preferred: 2 Unstained positively charged glass slide (25- x 75- x 1-mm) per test ordered; sections 4-microns thick
Acceptable: Formalin-fixed, paraffin-embedded (FFPE) tissue block
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/ihc-stains/
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/ihc-stains/#FAQ

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
Nonformalin fixed tissue	Reject
Nonparaffin embedded tissue	Reject
Noncharged slides	Reject
ProbeOn 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
TECHONLY	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information

The detection of calreticulin exon 9 frameshift alterations can assist in the diagnosis and prognostication of myeloproliferative diseases. Although these alterations are heterogeneous, they all result in a protein with a novel 36-amino acid C terminus the anticalreticulin CAL2 clone specifically identifies.

Most patients with essential thrombocythemia or primary myelofibrosis not associated with Janus kinase 2 (*JAK2*) or *MPL* variants are associated with *CALR* exon 9 variants and primary myelofibrosis patients carrying *CALR* variants have a more indolent clinical course.

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.

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. Vannucchi AM, Rotunno G, Bartalucci N, et al. Calreticulin mutation-specific immunostaining in myeloproliferative neoplasms: pathogenetic insight and diagnostic value. Leukemia. 2014;28(9):1811-1818. doi:10.1038/leu.2014.100
2. Stein H, Bob R, Durkop H, et al. A new monoclonal antibody (CAL2) detects CALRETICULIN mutations in formalin-fixed and paraffin-embedded bone marrow biopsies. Leukemia. 2016;30(1):131-135. doi:10.1038/leu.2015.192
3. Klampfl T, Gisslinger H, Harutyunyan AS, et al. Somatic mutations of Calreticulin in myeloproliferative neoplasms. N Engl J Med. 2013;369(25):2379-2390. doi:10.1056/NEJMoa1311347
4. Magaki S, Hojat SA, Wei B, So A, Yong WH. An introduction to the performance of immunohistochemistry. Methods Mol Biol. 2019;1897:289-298. doi:10.1007/978-1-4939-8935-5_25

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
CALRC	Calreticulin ex9mut IHC, Tech Only	Order only;no result

MAYO CLINIC LABORATORIES

Test Definition: CALRC

Calreticulin ex9mut Immunostain, Technical Component Only

Result ID	Test Result Name	Result LOINC® Value
71493	Calreticulin ex9mut IHC, Tech Only	Bill only; no result