MAYO CLINIC LABORATORIES

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Overview

Useful For
Aiding in the prognosis for patients diagnosed with heart failure

Risk stratification of patients with heart failure

An early indication of treatment failure and as a therapeutic target

Method Name
Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum Red

Specimen Required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Red top (serum gel/SST are **not acceptable**)
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot serum into plastic vial.

Forms
If not ordering electronically, complete, print, and send a [Cardiovascular Test Request Form](#) (T724) with the specimen.

Specimen Minimum Volume
0.2 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject

Specimen Stability Information

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Specimen Type	Temperature	Time	Special Container
Serum Red	Frozen (preferred)	365 days	
	Refrigerated	24 hours	

Clinical & Interpretive

Clinical Information

Heart failure is a complex cardiovascular disorder with a variety of etiologies and heterogeneity with respect to the clinical presentation of the patient. Heart failure is significantly increasing in prevalence with an aging population and is associated with high short- and long-term mortality rate. Over 80% of patients diagnosed and treated for acute heart failure syndromes in the emergency department are re-admitted within the forthcoming year, incurring costly treatments and therapies.

The development and progression of heart failure is a clinically silent process until manifestation of the disorder, which typically occurs late and irreversibly into its progression. Mechanistically, heart failure, whether due to systolic or diastolic dysfunction, is thought to progress primarily through adverse cardiac remodeling and fibrosis in response to cardiac injury or stress. Galectin-3 is a biomarker that appears to be actively involved in both the inflammatory and some fibrotic pathways.

Galectin-3 is a carbohydrate-binding lectin whose expression is associated with inflammatory cells, including macrophages, neutrophils, and mast cells. Galectin-3 has been linked to cardiovascular physiological processes including myofibroblast proliferation, tissue repair, and cardiac remodeling in the setting of heart failure. Concentrations of galectin-3 have been used to predict adverse remodeling after a variety of cardiac insults.

Reference Values

<24 months: Not established
2-17 years: < or =25.0 ng/mL
> or =18 years: < or =22.1 ng/mL

Interpretation

Clinically, galectin-3 concentrations may be categorized into 3 risk categories, substantiated by results from several large chronic heart failure studies:
< or =17.8 ng/mL (low risk)
17.9-25.9 ng/mL (intermediate risk)
>25.9 ng/mL (higher risk)

Results should be interpreted in the context of the individual patient presentation. Elevated galectin-3 results indicate an increased risk for adverse outcomes and signal the presence of galectin-3-mediated fibrosis and adverse remodeling. Once galectin-3 concentrations are elevated they are relatively stable over time in the absence of intervention.

Knowledge of a patient with heart failure's galectin-3 results may assist in risk stratification and lead to more aggressive management. There are no specific galectin-3 inhibitors available at this time, and patients with heart failure and elevated galectin-3 concentrations should be treated and monitored according to established guidelines. Angiotensin receptor blockers and aldosterone antagonists are thought to be particularly effective.

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A large multicenter, prospective, observational study was conducted to derive the reference intervals for galectin-3 that included 1092 subjects between the ages of 55 and 80 years without any known cardiac disease (520 males, 572 females). The 97.5th percentile of galectin-3 in that cohort was 22.1 ng/mL. Individuals with concentrations greater than 22.1 ng/mL had a significant association with mortality and New York Heart Association classification. However, this was an older population and definitive evidence of cardiac disease was not documented.

Cautions

Galectin-3 has not been shown to be useful in the acute diagnosis of heart failure, and natriuretic peptides (BNP or NT-proBNP) should be utilized for this purpose.

Hemolysis has been shown to interfere with the galectin-3 assay due to intracellular release of galectin-3. Specimens that are visibly hemolyzed will be rejected.

Heterophile antibodies, in particular human-antimouse antibodies in human serum, may cause falsely elevated galectin-3 results. Heterophile antibodies may react with reagent immunoglobulins and subsequently interfere with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous high or low values can be observed.

Patients with high concentrations of rheumatoid factor, as well as other autoimmune disorders, may also yield falsely elevated results and should be interpreted with caution.

Clinical Reference

1. Van der Velde AR, Meijers WC, Van den Heuvel ER, et al. Determinants of temporal changes in galectin-3 level in the general population: Data of PREVEND. Int J Cardiol. 2016;222:385-390. doi:10.1016/j.ijcard.2016.07.241
2. Mueller T, Gegenhuber A, Leitner I, et al. Diagnostic and prognostic accuracy of galectin-3 and soluble ST2 for acute heart failure. Clin Chim Acta. 2016;463:158-164. doi:10.1016/j.cca.2016.10.034
3. Sudharshan S, Novak E, Hock K, et al. Use of biomarkers to predict readmission for congestive heart failure. Am J Cardiol. 2017;119:445-451. doi:10.1016/j.amjcard.2016.10.022
4. Meijers WC, van der Velde AR, Muller Kobold AC, et al. Variability of biomarkers in patients with chronic heart failure and healthy controls. Eur J Heart Fail. 2017;19:357-365. doi:10.1002/ejhf.669
5. Meeusen JW, Johnson JN, Gray A, et al. Soluble ST2 and galectin-3 in pediatric patients without heart failure. Clin Biochem. 2015;48(18):1337-1340. doi:10.1016/j.clinbiochem.2015.08.007

Performance

Method Description

The galectin-3 assay is a diagnostic, quantitative 2-site manual enzyme-linked immunosorbent assay (ELISA) validated for use in human sera. The capture monoclonal antibody (rat IgG2a) is immobilized on 96-well plates, while the detection antibody utilizes a mouse monoclonal antibody that targets the human galectin-3 protein and is conjugated with horseradish peroxidase. This is an FDA 510K-cleared in vitro diagnostic device.(Package insert: BGM Galectin-3 Assay, BG Medicine, Inc. 05/2015)

PDF Report

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No

Day(s) Performed

Monday

Report Available

1 to 8 days

Specimen Retention Time

14 days

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

82777

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
GAL3	Galectin-3, S	62419-7

Result ID	Test Result Name	Result LOINC® Value
86202	Galectin-3, S	62419-7