MAYO CLINIC LABORATORIES

Test Definition: CH8B

Chromogenic Factor VIII Inhibitor Bethesda Titer, Plasma

Overview

Useful For

Detecting the presence and titer of a specific factor inhibitor directed against coagulation factor VIII

This test is **not useful** for detecting the presence of inhibitors directed against other clotting factors and **will not** detect the presence of lupus anticoagulants.

Special Instructions

- Coagulation Guidelines for Specimen Handling and Processing

Method Name

Only orderable as part of a profile. For more information see CHF8P / Chromogenic Factor VIII Inhibitor Bethesda Profile, Plasma.

Chromogenic

NY State Available

Yes

Specimen

Specimen Type

Plasma Na Cit

Specimen Required

Only orderable as part of a profile. For more information see CHF8P / Chromogenic Factor VIII Inhibitor Bethesda Profile, Plasma.

Specimen Type: Platelet-poor plasma
Collection Container/Tube: Light-blue top (3.2% sodium citrate)
Submission Container/Tube: Plastic vials
Specimen Volume: 2 mL Platelet-poor plasma in 2 plastic vials, each containing 1 mL
Collection Instructions:
1. Specimen **must be** collected prior to factor replacement therapy.
2. If collecting sample through a port/line, be sure to waste the appropriate amount prior to collection.
3. For complete instructions, see Coagulation Guidelines for Specimen Handling and Processing.
4. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.
5. Aliquot plasma (1 mL per aliquot) into 2 separate plastic vials leaving 0.25 mL in the bottom of centrifuged vial.
6. Immediately freeze plasma (no longer than 4 hours after collection) at -20 degrees C or, ideally -40 degrees C or below.

Additional Information:

1. Double-centrifuged specimen is critical for accurate results as platelet contamination may cause spurious results.
2. Each coagulation assay requested should have its own vial.

Specimen Minimum Volume

Platelet-poor plasma: 1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
IV heparin contamination	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma Na Cit	Frozen	14 days	

Clinical & Interpretive

Clinical Information

Factor VIII (FVIII) inhibitors are IgG antibodies directed against coagulation FVIII that typically result in development of potentially life-threatening hemorrhage. These antibodies may be alloimmune: developing in patients with congenital FVIII deficiency (hemophilia A) in response to therapeutic infusions of factor VIII concentrate or autoimmune: occurring in patients without hemophilia (not previously factor VIII deficient) either spontaneously, during pregnancy, or in association with autoimmune diseases.

Reference Values

Only orderable as part of a profile. For more information see CHF8P / Chromogenic Factor VIII Inhibitor Bethesda Profile, Plasma.

< or =0.5 Bethesda Units

Interpretation

The interpretive report will include assay information, background information, and conclusions based on the test results.

Cautions

Contamination with excess heparin and hemodilution due to improper specimen collection through an intravenous access device or collection above a running intravenous fluid line may cause spurious results.

Clinical Reference

1. Verbruggen B, van Heerde WL, Laros-van Gorkom BA. Improvements in factor VIII inhibitor detection: From Bethesda to Nijmegen. Semin Thromb Hemost. 2009;35(8):752-759
2. Miller CH, Platt SJ, Rice AS, Kelly F, Soucie JM. Hemophilia Inhibitor Research Study Investigators. Validation of Nijmegen-Bethesda assay modifications to allow inhibitor measurement during replacement therapy and facilitate inhibitor surveillance. J Thromb Haemost. 2012;10(6):1055-1061

Performance

Method Description

In the Bethesda procedure, patient plasma is heat-inactivated (HI) at 56 degrees C for 30 minutes. Next using the HI patient plasma, serial dilutions are prepared and mixed in equal volumes with normal pooled plasma. The mixture is incubated 2 hours at 37 degrees C. At the end of the incubation, chromogenic factor VIII (CH8) activity is measured and compared to a control performed at the same time. The difference between the CH8 activity of the patient's incubation mixture and that of the control is used to calculate the titer. The residual CH8 activity is converted to Bethesda units: 50% residual CH8 is equal to 1 Bethesda unit. Assays using the same basic principle as the Bethesda assay are used to quantitate the inhibitors of the other coagulation factors.(Kasper CK, Aldedort LM, Counts RB, et al. A more uniform measurement of factor VIII inhibitors. Thromb Diath Haemorrh. 1975;34[03]:869-872. doi:10.1055/s-0038-1651378; Miller CH. Laboratory testing for factor VIII and IX inhibitors in haemophilia: A review. Haemophilia. 2018;24[2]:186-197. doi:10.1111/hae.1342)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

2 days

Specimen Retention Time

7 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.

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Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

85335

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CH8B	Chromogenic FVIII Inhibitor Titer,P	93450-5

Result ID	Test Result Name	Result LOINC® Value
CH8B	Chromogenic FVIII Inhibitor Titer,P	93450-5