MAYO CLINIC LABORATORIES

Test Definition: 11INE

Factor XI Inhibitor Evaluation, Plasma

Overview

Useful For

Detection and quantitation of inhibitor to coagulation factor XI

This test is **not useful** for the detection of a lupus-like circulating anticoagulant inhibitor, a nonspecific circulating anticoagulant, or other inhibitors that are not specific for coagulation factors.

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
11INT	FXI Inhib Profile Tech Interp	No	Yes
F_11	Coag Factor XI Assay, P	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
11AIH	FXI Inhib Profile Prof Interp	No	No
11_IS	Factor XI Inhib Scrn	No	No
GBETH	General Factor Bethesda Units, P	No	No

Testing Algorithm

Testing begins with the coagulation factor XI activity assay with dilutions to evaluate assay inhibition; if the factor XI activity assay is normal or increased, then a technical interpretation will be provided.

If the factor XI activity assay is decreased, then an inhibitor screen to look for specific factor XI inhibition will be performed at an additional charge and a professional interpretation will be provided. If specific inhibition is apparent, the titer of the inhibitor will be determined.

Special Instructions

- Coagulation Guidelines for Specimen Handling and Processing

Method Name

F_11, 11_IS, GBETH: Optical Clot-Based
11INT: Technical Interpretation
11AIH: Medical Interpretation

NY State Available

Yes

Specimen

Specimen Type
Plasma Na Cit

Ordering Guidance
This test is for factor XI inhibitors only. If the presence or type of inhibitor is unknown, first order APROL / Prolonged Clot Time Profile, Plasma, except for patients with known hemophilia A or B. When screening studies are needed for patients with known hemophilia A or B, order 8INHE / Factor VIII Inhibitor Evaluation, Plasma; or 9INHE / Factor IX Inhibitor Evaluation, Plasma; respectively.

Shipping Instructions
Send all vials in the same shipping container.

Specimen Required
Specimen Type: Platelet-poor plasma
Patient Preparation:
1. Patient **should not** be receiving anticoagulant treatment (eg, warfarin, heparin). If not possible for medical reasons, note on request.
 a. If medically feasible, for 4 to 6 hours before specimen collection, **do not** administer intravenous heparin.
 b. If medically feasible, for 10 to 14 days before specimen collection, **do not** administer subcutaneous heparin or warfarin**.**
2. Patient **should not** be receiving fibrinolytic agents (streptokinase, urokinase, tissue plasminogen activator [tPA]).
3. It is recommended that specimens be collected pretransfusion. If patient has been transfused, **a specimen should not be collected for 48 hours.**
Collection Container/Tube: Light-blue top (3.2% sodium citrate)
Submission Container/Tube: 13-mm x 75-mm, 5-mL, plastic vial (polypropylene preferred)
Specimen Volume: 3 mL Platelet-poor plasma in 3 plastic vials, each containing 1 mL
Collection Instructions:
1. Specimen must be collected prior to factor replacement therapy.
2. For complete instructions, see Coagulation Guidelines for Specimen Handling and Processing.
3. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.
4. Aliquot plasma (1-2 mL per aliquot) into 3 separate plastic vials, leaving 0.25 mL in the bottom of centrifuged vial.
5. Immediately freeze plasma at -20 degrees C or, ideally, at -40 degrees C or below.
Additional Information:
1. A 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.

Forms
If not ordering electronically, complete, print, and send a Coagulation Test Request (T753) with the specimen.

Specimen Minimum Volume
Platelet-poor plasma: 2 Plastic vials, each containing 1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Factor XI inhibitors typically arise in patients with congenital XI deficiency (hemophilia C) or after infusion of fresh frozen plasma or factor XI concentrates. Acquired factor XI inhibitors rarely occur spontaneously.

Reference Values

FACTOR XI ACTIVITY ASSAY

Adults: 55-150%

Normal, full-term infants or healthy premature infants may have decreased levels (> or =10%) that may not reach adult levels for 180 days or more postnatal.*

*See Pediatric Hemostasis References section in Coagulation Guidelines for Specimen Handling and Processing.

FACTOR XI INHIBITOR SCREEN:

Negative

GENERAL FACTOR BETHESDA UNITS:

< or =0.5 Bethesda Units

Interpretation

Normally, there is no inhibitor, ie, negative.

If the screening assays indicate the presence of an inhibitor, it will be quantitated and reported in Bethesda (or equivalent) units.

Cautions

Occasionally, a potent lupus-like anticoagulant may cause false-positive testing for a specific factor inhibitor (eg, factor VIII or IX); see Ordering Guidance.

Clinical Reference

1. Hoffman R, Benz Jr EJ, Silberstein LE, et al, eds: Hematology: Basic Principles and Practice. 7th ed. Elsevier; 2018
2. Kasper CK. Treatment of factor VIII inhibitors. Prog Hemost Thromb. 1989;9:57-86
3. Kottke-Marchant K, ed. Laboratory Hematology Practice. Wiley Blackwell Publishing; 2012

Performance

Method Description

The factor XI assay is performed on the Instrumentation Laboratory ACL TOP using the activated partial thromboplastin time (aPTT) method and a factor-deficient substrate. Patient plasma is combined and incubated with a factor XI-deficient substrate (normal plasma depleted of factor XI by immunoadsorption) and an aPTT reagent. After a specified incubation time, calcium is added to trigger the coagulation process in the mixture. Then the time to clot formation is measured optically at a wavelength of 671 nm.(Owen CA Jr, Bowie EJW, Thompson JH Jr. Diagnosis of Bleeding Disorders. 2nd ed. Little, Brown and Company; 1975; Cielsa B. Defects of plasma clotting factors. In: Hematology in Practice. 3rd ed. FA Davis; 2019:chap 17)

The factor XI inhibitor screen consists of measuring the difference in factor XI activity (aPTT-based assay) before and after incubation of a mixture of normal plasma and patient's plasma for 1 hour at 37 degrees C. For optimal sensitivity, the factor XI value of the normal plasma is adjusted to approximately 20%, because the factor XI assay is more sensitive in this area of the curve. In addition, an excess of patient's plasma will make the test more sensitive to small amounts of inhibitors.(Owen CA Jr, Bowie EJW, Thompson JH Jr. The Diagnosis of Bleeding Disorders. 2nd ed. Little, Brown, and Company, 1975, pp 143-145; Cielsa B. Defects of plasma clotting factors. In: Hematology in Practice. 3rd ed. FA Davis; 2019:chap 17)

If the inhibitor screen is positive for an inhibitor of factor XI, the inhibitor will be quantitated by the Bethesda assay. In the Bethesda procedure, inhibitors are quantified by mixing equal volumes of serially diluted plasma with normal plasma. This mixture is incubated 2 hours at 37 degrees C, and the factor XI activity is measured and compared to a control run at the same time. The difference between the factor XI activity of the patient's incubation mixture and that of the control is used to calculate titer. The residual factor XI activity is converted to Bethesda units: 50% residual factor XI is equal to 1 Bethesda unit.(Kasper CK, Aldedort LM, Counts RB, et al. A more uniform measurement of factor VIII inhibitors. Thromb Diath Haemorrh. 1975;34:869-872; Cielsa B. Defects of plasma clotting factors. In: Hematology in Practice. 3rd ed. FA Davis; 2019:chap 17)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 3 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.

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

85390
85270
85335 (if appropriate)
85335 (if appropriate)
85390 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
11INE	Factor XI Inhib Profile, P	96453-6

Result ID	Test Result Name	Result LOINC® Value
F_11	Coag Factor XI Assay, P	3226-8
11INT	FXI Inhib Profile Tech Interp	69049-5