

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 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 will be performed at an additional charge to look for specific factor XI inhibition 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 9 INHE / 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. Fasting: 8 hours, preferred but not required
2. Patient should not be receiving Coumadin (warfarin), heparin, direct thrombin inhibitors (argatroban, dabigatran), or direct factor Xa inhibitors (apixaban, rivaroxaban, and edoxaban).

Collection Container/Tube: Light-blue top (3.2% sodium citrate)

Submission Container/Tube: Polypropylene plastic vials

Specimen Volume: 3 mL 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. Freeze plasma immediately 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

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 newborn 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

This assay consists of measuring the difference in factor XI activity (activated partial thromboplastin time-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 |