

## 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.

### 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](#)

### 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

### Method Name

Optical Clot-Based

### NY State Available

Yes

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**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, order APROL / Prolonged Clot Time Profile, Plasma first, except for when screening studies are needed for patients with known hemophilia A or B.

**Shipping Instructions**

Send all vials in the same shipping container.

**Necessary Information**

If priority specimen, mark request form, give reason, and request a call-back.

**Specimen Required****Patient Preparation:**

1. Patient should not be receiving Coumadin (warfarin), heparin, direct thrombin inhibitors (argatroban, dabigatran), or direct factor Xa inhibitors (apixaban, rivaroxaban, and edoxaban).
2. Fasting preferred.

**Specimen Type:** Platelet-poor plasma

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

**Submission Container/Tube:** 3 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](#) in Special Instructions.
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 (no longer than 4 hours after collection) at -20 degrees C or, ideally, < or =-40 degrees C.

**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.

**Forms**

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

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

**Specimen Minimum Volume**

2 mL plasma in 2 plastic vials, 1 mL each

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Plasma Na Cit	Frozen (preferred)	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%) which may not reach adult levels for > or =180 days postnatal.\*

\*See Pediatric Hemostasis References section in [Coagulation Guidelines for Specimen Handling and Processing](#) in Special Instructions.

**Interpretation**

Normally, there is no inhibitor, ie, negative.

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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. Hematology: Basic Principles and Practice. Seventh edition. Edited by R Hoffman, EJ Benz Jr, LE Silberstein, et al. Elsevier, 2018
2. Kasper CK: Treatment of factor VIII inhibitors. *Prog Hemost Thromb* 1989;9:57-86
3. Laboratory Hematology Practice. Edited by K Kottke-Marchant. 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. Second edition. Little, Brown, and Company, 1975, pp 143-145; Meijer P, Verbruggen and Spannagi M: Chapter 33: Clotting factors and inhibitors: Assays and Interpretation. In Laboratory Hematology Practice. Edited by K Kottke-Marchant. Wiley Blackwell Publishing, 2012, pp 435-446)

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; Meijer P, Verbruggen and Spannagi M: Chapter 33: Clotting factors and inhibitors: Assays and Interpretation. In Laboratory Hematology Practice. Edited by K Kottke-Marchant. Wiley Blackwell Publishing, 2012, pp 435-446)

**PDF Report**

No

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Rochester

**Fees & Codes**

**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-Factor XI Tech Interp

85270-Factor XI Assay

85335-Factor inhibitor Scrn (if appropriate)

85335-Bethesda units (if appropriate)

85390-Factor XI Professional Interp (if appropriate)

**LOINC® Information**

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

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