Overview

Useful For
Detection and quantitation of inhibitor to coagulation factor XI

This test is **not useful** for detecting presence of inhibitors directed against other clotting factors and is **not useful** for the detection of a nonspecific circulating anticoagulant.

This test is **not useful** for the detection of lupus anticoagulants.

Profile Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>F_11</td>
<td>Coag Factor XI Assay, P</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>11_IS</td>
<td>Factor XI Inhib Scrn</td>
<td>No</td>
<td>Yes</td>
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Reflex Tests

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<th>Reporting Name</th>
<th>Available Separately</th>
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<tr>
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<td>Bethesda Units</td>
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<tr>
<td>11_IS</td>
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<td>No</td>
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<tr>
<td>CCCR</td>
<td>Special Coagulation Interpretation</td>
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</table>

Testing Algorithm
Testing begins with coagulation factor XI activity assay with dilutions to evaluate assay inhibition; if the factor XI activity assay is decreased, an inhibitor screen will be performed to look for specific factor XI inhibition. If specific inhibition is apparent, the titer of the inhibitor will be determined.

Special Instructions
- [Coagulation Studies](#)

Method Name
Optical Clot-Based

NY State Available
Yes

Specimen

Specimen Type
Plasma Na Cit
Advisory Information
This test is for factor XI inhibitors only. If the presence or type of inhibitor is unknown, LUPPR / Lupus Anticoagulant Profile should be ordered first, except for screening studies in patients with known hemophilia A or B.

Shipping Instructions
Send all vials in the same shipping container.

Specimen Required

Patient Preparation: Fasting preferred

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

Submission Container/Tube: Plastic vials

Specimen Volume: 3 mL in 3 plastic vials each containing 1 mL

Collection Instructions:
1. Specimen must be drawn prior to factor replacement therapy.
2. Spin down, remove plasma, and spin plasma again.
3. 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. If priority specimen, mark request form, give reason, and request a call-back.
3. 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 mL in 2 plastic vials, 1 mL each

Reject Due To

<table>
<thead>
<tr>
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<th>Mild OK; Gross reject</th>
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<tr>
<td>Hemolysis</td>
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<tr>
<td>Lipemia</td>
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<tr>
<td>Icterus</td>
<td>Mild OK; Gross reject</td>
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<tr>
<td>Other</td>
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Specimen Stability Information
**Clinical and Interpretive**

**Clinical Information**
Factor XI inhibitors typically arise in patients with congenital XI deficiency (hemophilia C), 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 (≥10%) which may not reach adult levels for ≥180 days postnatal.*

*See Pediatric Hemostasis References in **Coagulation Studies** in Special Instructions.

**FACTOR XI INHIBITOR SCREEN**

Negative

**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 Advisory Information.

**Clinical Reference**


**Performance**

**Method Description**

This assay consists of measuring the difference in factor XI activity (activated partial thromboplastin time 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
Test Definition: F11IS
Coag Factor XI Inhibitor Scrn, P


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)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
7 Days

Performing Laboratory Location
Rochester

Fees and 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 Regional Manager. For assistance, contact Customer Service.

Test Classification
See Individual Test IDs

CPT Code Information
85270-Factor XI
85335-Factor inhibitor
85335-Bethesda units (if appropriate)

LOINC® Information
## Test Definition: F11IS
Coag Factor XI Inhibitor Scrn, P

<table>
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<td>Coag Factor XI Inhibitor Scrn, P</td>
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<table>
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<td>F_11</td>
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