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.

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>F8A</td>
<td>Coag Factor VIII Activity Assay, P</td>
<td>Yes</td>
<td>Yes</td>
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Reflex Tests

<table>
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<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
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<tbody>
<tr>
<td>IBETH</td>
<td>Bethesda Units</td>
<td>No</td>
<td>No</td>
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<tr>
<td>F8IS</td>
<td>Coag Factor VIII Assay Inhib Scrn,P</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>CCCR</td>
<td>Special Coagulation Interpretation</td>
<td>No</td>
<td>No</td>
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</tbody>
</table>

Testing Algorithm

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

Special Instructions

- [Coagulation Guidelines for Specimen Handling and Processing](#)
- [Coagulation Profile Comparison](#)

Method Name

Optical Clot-Based

NY State Available

Yes

Specimen

Specimen Type

Plasma Na Cit
Advisory Information
This test is for factor VIII inhibitors only. If the presence or type of inhibitor is unknown, order either APROL / Prolonged Clot Time Profile, Plasma or ALUPP / Lupus Anticoagulant Profile, Plasma first.

Multiple coagulation profile tests are available. See Coagulation Profile Comparison in Special Instructions for testing that is performed with each profile.

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
See Coagulation Guidelines for Specimen Handling and Processing in Special Instructions.

Patient Preparation: Fasting preferred

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

Submission Container/Tube: 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. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.
3. Aliquot plasma into 3 separate plastic vials (1 mL in each) leaving 0.25 mL in the bottom of centrifuged vial.
4. Freeze plasma immediately (no longer than 4 hours after collection) at-20 degrees C or, ideally, < or =-40 degreesC.

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.

Specimen Minimum Volume
2 mL in 2 plastic vials, 1 mL each

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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</table>

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Test Definition: F8INH
Factor 8 Inhib Prof

Specimen Stability Information

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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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</thead>
<tbody>
<tr>
<td>Plasma Na Cit</td>
<td>Frozen</td>
<td>14 days</td>
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Clinical and 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 develop in 1 of 4 different patient populations:

- Patients with congenital FVIII deficiency (hemophilia A) in response to therapeutic infusions of factor VIII concentrate
- Elderly nonhemophiliac patients (not previously factor VIII deficient)
- Women in postpartum period
- Patients with other autoimmune illnesses

Reference Values

FACTOR VIII ACTIVITY ASSAY

Adults: 55-200%

Normal, full-term newborn infants or healthy premature infants usually have normal or elevated factor VIII. *

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

FACTOR VIII INHIBITOR SCREEN

Negative

BETHESDA TITER

0 Units

Interpretation

Normally, there is no inhibitor (ie, negative result).

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 results for a specific factor inhibitor (eg, factor VIII or IX). See Advisory Information.

**Clinical Reference**


**Performance**

**Method Description**


The factor VIII inhibitor screen consists of measuring the difference in factor VIII activity (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 VIII value of the normal plasma is adjusted to approximately 20%, because the factor VIII 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, Boston, MA, 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 VIII, 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 its factor VIII activity is measured and compared to a control run at the same time. The difference between the factor VIII activity of the patient's incubation mixture and that of the control is used to calculate the titer. The residual factor VIII activity is converted to Bethesda units: 50% residual factor VIII 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;34:869-872; 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

**Day(s) and Time(s) Test Performed**

Monday through Friday; Varies
**Test Definition: F8INH**
Factor 8 Inhib Prof

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**Analytic Time**
2 days

**Maximum Laboratory Time**
3 days

**Specimen Retention Time**
7 Days

**Performing Laboratory Location**
Rochester

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**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**
85240-Factor VIII activity assay

85335-Bethesda titer (if appropriate)

85335-Factor VIII inhibitor screen (if appropriate)

85390-26-Special coagulation interpretation (if appropriate)

**LOINC® Information**

<table>
<thead>
<tr>
<th>Test ID</th>
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<th>Order LOINC Value</th>
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<tr>
<td>F8INH</td>
<td>Factor 8 Inhib Prof</td>
<td>3209-4</td>
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<table>
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