Overview

Useful For
Diagnosing deficiencies, particularly hemophilia B (Christmas disease)

Assessing the impact of liver disease on hemostasis

Investigation of a prolonged activated partial thromboplastin time

Testing Algorithm
See Hemophilia Testing Algorithm in Special Instructions.

Special Instructions
- Coagulation Guidelines for Specimen Handling and Processing
- Hemophilia Testing Algorithm

Method Name
Optical Clot-Based

NY State Available
Yes

Specimen

Specimen Type
Plasma Na Cit

Advisory Information
Coagulation testing is highly complex, often requiring the performance of multiple assays and correlation with clinical information. For that reason we suggest ordering Coagulation Consultations.

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

Specimen Required

Specimen Type: Platelet-poor plasma

Patient Preparation: Patient must not be receiving Coumadin or heparin therapy.

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

Submission Container/Tube: Plastic vial

Specimen Volume: 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 into a plastic vial, 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.

Specimen Minimum Volume
0.5 mL

Reject Due To

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>Reject</td>
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<tr>
<td>Gross icterus</td>
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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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<tbody>
<tr>
<td>Plasma Na Cit</td>
<td>Frozen</td>
<td>14 days</td>
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Clinical and Interpretive

Clinical Information

Factor IX is a vitamin K-dependent serine protease synthesized in the liver and participates in the intrinsic coagulation pathway. Its biological half-life is 18 to 24 hours.

Congenital deficiency inherited as an X-linked recessive bleeding disorder (hemophilia B). Severe deficiency (<1%) characterized by hemarthroses, deep tissue bleeding, excessive bleeding with trauma and ecchymoses.

Acquired deficiency associated with liver disease, vitamin K deficiency, warfarin therapy and inhibitors (rare).

Reference Values

< or = 6 months: Normal, full-term newborn infants or healthy premature infants may have decreased levels (> or = 20%) which may not reach adult levels for > or = 180 days postnatal.* (Literature derived)
Test Definition: F_9
Coag Factor IX Assay, P

>6 months: 65-140%

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

**Interpretation**
Acquired deficiency is more common than congenital.

Mild hemophilia B: 5% to 50%

Moderate hemophilia B: 1% to 5%

Severe hemophilia B: <1%

**Cautions**
Liver disease, warfarin therapy, or vitamin K deficiency may lower factor IX levels.

**Clinical Reference**


**Performance**

**Method Description**
The factor IX 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 IX-deficient substrate (normal plasma depleted of factor IX 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; Meijer P, Verbruggen and Spannagi M: Clotting factors and inhibitors: assays and interpretation. In: Kottke-Marchant K, ed. Laboratory Hematology Practice. Wiley Blackwell Publishing; 2012:435-446)

**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
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 U.S. Food and Drug Administration.

CPT Code Information
85250

LOINC® Information

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<tr>
<td>F_9</td>
<td>Coag Factor IX Assay, P</td>
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