

## 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

For information see [Hemophilia Testing Algorithm](#)

### 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

### Ordering Guidance

Coagulation testing is highly complex, often requiring the performance of multiple assays and correlation with clinical information. For that reason, consider ordering a Coagulation Consultation.

### 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 (warfarin) 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](#).
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, at or below -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**

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

Acquired deficiency is 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 180 or more days postnatal.\* (Literature derived)

>6 months: 65-140%

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

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**Interpretation**

Acquired deficiency is more common than congenital.

Mild hemophilia B: 5% to 50% activity

Moderate hemophilia B: 1% to 5% activity

Severe hemophilia B: <1% activity

**Cautions**

Liver disease, warfarin therapy, or vitamin K deficiency may decrease factor IX levels.

**Clinical Reference**

1. Barrowcliffe TW, Raut S, Sands D, Hubbard AR. Coagulation and chromogenic assays of factor VIII activity: general aspects, standardization, and recommendations. *Semin Thromb Hemost.* 2002;28(3):247-256
2. Franchini M, Lippi G, Favaloro EJ. Acquired inhibitors of coagulation factors: part II. *Semin Thromb Hemost.* 2012;38(5):447-453
3. Carcao MD. The diagnosis and management of congenital hemophilia. *Semin Thromb Hemost.* 2012;38(7):727-734
4. Favaloro EJ, Lippi G, eds. *Hemostasis and Thrombosis: Methods and Protocols.* Humana Press; 2017

**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; 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 Saturday

**Report Available**

1 to 3 days

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Rochester

**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**

85250

**LOINC® Information**

| Test ID | Test Order Name         | Order LOINC® Value |
|---------|-------------------------|--------------------|
| F_9     | Coag Factor IX Assay, P | 3187-2             |

| Result ID | Test Result Name        | Result LOINC® Value |
|-----------|-------------------------|---------------------|
| F_9       | Coag Factor IX Assay, P | 3187-2              |