

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

No

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](#).

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; Meijer P, Verbruggen HW, 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) Performed

Monday through Friday

Report Available

1 to 3 days

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

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 |