MAYO CLINIC LABORATORIES

# Test Definition: F_9

Coagulation Factor IX Activity Assay, Plasma

## 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:**

1. Patient **should not** be receiving anticoagulant treatment (eg, warfarin, heparin). If not possible for medical reasons, note on request.

a. If medically feasible, for 4 to 6 hours before specimen collection, **do not** administer intravenous heparin.

b. If medically feasible, for 10 to 14 days before specimen collection, **do not** administer subcutaneous heparin or

warfarin**.**

2. Patient **should not** be receiving fibrinolytic agents (streptokinase, urokinase, tissue plasminogen activator [tPA]).

3. It is recommended that specimens be collected pretransfusion. If patient has been transfused, **a specimen should not be collected for 48 hours.**

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

**Submission Container/Tube**: 13-mm x 75-mm, 5-mL, plastic vial (polypropylene preferred)

**Specimen Volume:** 1 mL Platelet-poor plasma

**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. Immediately freeze plasma (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

Platelet-poor plasma: 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 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 |