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