MAYO CLINIC LABORATORIES

Test Definition: 7INHE

Factor VII Inhib Profile, P

Overview

Useful For

Detection and quantitation of inhibitor to coagulation factor VII

This test is **not useful** for the detection of a lupus-like circulating anticoagulant inhibitor, a nonspecific circulating anticoagulant, or other inhibitors that are not specific for coagulation factors.

Testing Algorithm

Testing begins with coagulation factor VII activity assay with dilutions to evaluate assay inhibition; if the factor VII activity assay is normal or increased, a technical interpretation will be provided. If the factor VII activity assay is decreased, an inhibitor screen will be performed at an additional charge to look for specific factor VII inhibition and a professional interpretation will be provided. If specific inhibition is apparent, the titer of the inhibitor will be determined.

Special Instructions

- Coagulation Guidelines for Specimen Handling and Processing

Profile Information

Test Id	Reporting Name	Available Separately	Always Performed
7INHT	FVII Inhib Profile Tech Interp	No	Yes
F_7	Coag Factor VII Assay, P	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
7AINH	FVII Inhib Profile Prof Interp	No	No
F7_IS	Factor VII Inhib Scrn	No	No
GBETH	General Factor Bethesda Units, P	No	No

Method Name

Optical Clot-Based

NY State Available

Yes

Specimen

Specimen Type
Plasma Na Cit

Ordering Guidance
This test is for factor VII inhibitors only. If the presence or type of inhibitor is unknown, order APROL / Prolonged Clot Time Profile, Plasma first, except for screening studies in patients with known hemophilia A or B.

Shipping Instructions
Send all vials in the same shipping container.

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

Specimen Required
Patient Preparation:

1. Patient must not be receiving Coumadin (warfarin) or heparin therapy.

2. Fasting preferred

Specimen Type: Platelet-poor plasma

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

Submission Container/Tube: Plastic vial

Specimen Volume: 3 mL in 3 plastic vials, each containing 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 (1-2 mL per aliquot) into 3 separate plastic vials 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.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Minimum Volume

2 mL in 2 plastic vials, 1 mL each

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma Na Cit	Frozen (preferred)	14 days	

Clinical & Interpretive

Clinical Information

Coagulation factor inhibitors arise in patients who are congenitally deficient in a specific factor in response to factor replacement therapy, or can occur spontaneously without known cause or in response to a variety of medical conditions including the postpartum state, immunologic disorders, certain antibiotic therapies, some malignancies, and old age.

Inhibitors of factor VIII coagulant activity are the most commonly occurring of the specific factor inhibitors.

Reference Values

FACTOR VII ACTIVITY ASSAY

Adults: 65-180%

Normal, full-term newborn infants or healthy premature infants may have decreased levels (> or =20%), which increase within the first postnatal week but may not reach adult levels for > or =180 days postnatal.*

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

Interpretation

Normally, there is no inhibitor, ie, negative result.

If the screening assays indicate the presence of an inhibitor, it will be quantitated and reported in Bethesda (or equivalent) units.

Cautions

Occasionally, a potent lupus-like anticoagulant may cause false-positive testing for a specific factor inhibitor (eg, factor VIII or IX); see Ordering Guidance.

Clinical Reference

1. Hematology: Basic Principles and Practice. Seventh Edition. Edited by R Hoffman, EJ Benz Jr, LE Silberstein, et al. Elsevier, 2018

2. Kasper CK: Treatment of factor VIII inhibitors. Prog Hemost Thromb 1989;9:57-86

3. Laboratory Hematology Practice. Edited by K Kottke-Marchant. Wiley Blackwell Publishing, 2012

Performance

Method Description

Screening for inhibitors of specific coagulation factors is represented by the inhibitor assay for factor VII. This assay consists of measuring the difference in factor VII activity (prothrombin time based assay) before and after incubation of a mixture of normal plasma and patient's plasma for 1 hour at 37 degrees C. For optimal sensitivity, the factor VII value of the normal plasma is adjusted to approximately 20% because the factor VII assay is more sensitive in this area of the curve. In addition, an excess of patient's plasma will make the test more sensitive to small amounts of inhibitors.(Owen CA Jr, Bowie EJW, Thompson JH Jr: The Diagnosis of Bleeding Disorders. Second edition. Little, Brown, and Company, 1975, pp 143-145; Meijer P, Verbruggen and Spannagi M: Chapter 33: Clotting factors and inhibitors: Assays and Interpretation. In Laboratory Hematology Practice. Edited by K Kottke-Marchant. Wiley Blackwell Publishing, 2012, pp 435-446)

If the inhibitor screen is positive for an inhibitor of factor VII, the inhibitor will be quantitated by the "Bethesda assay." In the Bethesda procedure, inhibitors are quantified by mixing equal volumes of serially diluted plasma with normal plasma. This mixture is incubated 2 hours at 37 degrees C, and its factor VII activity is measured and compared to a control run at the same time. The difference between the factor VII activity of the patient's incubation mixture and that of the control is used to calculate titer. The residual factor VII activity is converted to "Bethesda units": 50% residual factor VII is equal to 1 Bethesda unit.(Kasper CK, Aldedort LM, Counts RB, et al: A more uniform measurement of factor VIII inhibitors. Thromb Diath Haemorrh 1975;34:869-872; Meijer P, Verbruggen and Spannagi M: Chapter 33: Clotting

factors and inhibitors: Assays and Interpretation. In Laboratory Hematology Practice. Edited by K Kottke-Marchant. Wiley Blackwell Publishing, 2012, pp 435-446)

PDF Report
No

Specimen Retention Time
7 days

Performing Laboratory Location
Rochester

Fees & Codes

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
85390-FVII Tech Interp

85230-Factor VII

85335-Factor inhibitor (if appropriate)

85335-Bethesda units (if appropriate)

85390-Factor VII Professional interp (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
7INHE	Factor VII Inhib Profile, P	90225-4

Result ID	Reporting Name	LOINC®
F_7	Coag Factor VII Assay, P	3198-9
7INHT	FVII Inhib Profile Tech Interp	69049-5