Test Definition: 2INHE

Factor II Inhib Profile, P

Overview

Useful For

Detection and quantitation of inhibitor to factor II

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 II activity assay with dilutions to evaluate assay inhibition; if the factor II activity assay is normal or increased, a technical interpretation will be provided. If the factor II activity assay is decreased, an inhibitor screen will be performed at an additional charge to look for specific factor II 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
2INHT	FII Inhib Profile Tech Interp	No	Yes
F_2	Coag Factor II Assay, P	Yes	Yes

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
2AINH	FII Inhib Profile Prof Interp	No	No
F2_IS	Factor II 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 II inhibitors only. If the presence or type of inhibitor is unknown, order APROL / Prolonged Clot Time Profile, Plasma first, except for when screening studies are needed for 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 vials

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 1-2 mL of plasma 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 either 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 in geriatric patients.

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

Reference Values

FACTOR II ACTIVITY ASSAY

Adults: 75-145%

Normal, full-term newborn infants or healthy premature infants may have decreased levels (> or =25%) which may remain below 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 II. This assay consists of measuring the difference in factor II 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 II value of the normal plasma is adjusted to approximately 20%, because the factor II 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 II, 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 II activity is measured and compared to a control run at the same time. The difference between the factor II activity of the patient's incubation mixture and that of the control is used to calculate the titer. The residual factor II activity is converted to "Bethesda units": 50% residual factor II 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 - Factor II Tech Interp

85210 - Factor II

85335 - Factor inhibitor (if appropriate)

85335 - Bethesda units (if appropriate)

85390 - Factor II Professional Interp (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
2INHE	Factor II Inhib Profile, P	96455-1

Result ID	Reporting Name	LOINC®
F_2	Coag Factor II Assay, P	3289-6
2INHT	FII Inhib Profile Tech Interp	69049-5