MAYO CLINIC LABORATORIES

# Test Definition: 10INE

Factor X Inhibitor Evaluation, Plasma

## Overview

### Useful For

Detection and quantitation of inhibitor to coagulation factor X

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.

### Profile Information

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| 10INT | FX Inhib Profile Tech Interp | No | Yes |
| F_10 | Coag Factor X Assay, P | Yes | Yes |

### Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---|---|---|---|
| 10AIH | FX Inhib Profile Prof Interp | No | No |
| 10_IS | Factor X Inhib Scrn | No | No |
| GBETH | General Factor Bethesda Units, P | No | No |

### Testing Algorithm

Testing begins with the coagulation factor X activity assay with dilutions to evaluate assay inhibition; if the factor X activity assay is normal or increased, then a technical interpretation will be provided.

If the factor X activity assay is decreased, then an inhibitor screen to look for specific factor X inhibition will be performed at an additional charge 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

### Method Name

F_10, 10_IS, GBETH: Optical Clot-Based
10INT: Technical Interpretation
10AIH: Medical Interpretation

### NY State Available

Yes

## Specimen

### Specimen Type
Plasma Na Cit

### Ordering Guidance
This test is for factor X inhibitors only. If the presence or type of inhibitor is unknown, first order APROL / Prolonged Clot Time Profile, Plasma, except for patients with known hemophilia A or B. When screening studies are needed for patients with known hemophilia A or B, order 8INHE / Factor VIII Inhibitor Evaluation, Plasma; or 9INHE / Factor IX Inhibitor Evaluation, Plasma; respectively.

### Shipping Instructions
Send all vials in the same shipping container.

### 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:** 3 mL Platelet-poor plasma 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.
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. Immediately freeze plasma (no longer than 4 hours after collection) at -20 degrees C or, ideally, -40 degrees C or below.
**Additional Information:**
1. A 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: 2 Plastic vials, each containing 1 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

Coagulation factor inhibitors arise in patients who are congenitally deficient in a specific factor in response to factor replacement therapy, or they 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 the older population.

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

### Reference Values

FACTOR X ACTIVITY ASSAY
Adults: 70-150%
Normal, full-term infants or healthy premature infants may have decreased levels (> or =15-20%) that may not reach adult levels for 180 days or more postnatal.*
*See Pediatric Hemostasis References section in Coagulation Guidelines for Specimen Handling and Processing.

FACTOR X INHIBITOR SCREEN:
Negative

GENERAL FACTOR BETHESDA UNITS:
< or =0.5 Bethesda Units

### 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).

### Clinical Reference

1. Hoffman R, Benz Jr EJ, Silberstein LE, et al, eds. Hematology: Basic Principles and Practice. 7th ed. Elsevier; 2018
2. Kasper CK. Treatment of factor VIII inhibitors. Prog Hemost Thromb. 1989;9:57-86

## Performance

### Method Description

The factor X assay is performed on the Instrumentation Laboratory ACL TOP using the prothrombin time (PT) method and a factor-deficient substrate. Patient plasma is combined and incubated with a factor X-deficient substrate (normal plasma depleted of factor X by immunoadsorption). After a specified incubation time, a PT reagent 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. Second edition. Little, Brown and Company, Boston, MA. 1975; Cielsa B. Defects of plasma clotting factors. In: Hematology in Practice. 3rd ed. FA Davis; 2019:chap 17)

The factor X inhibitor screen consists of measuring the difference in factor X activity (PT-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 X value of the normal plasma is adjusted to approximately 20%, because the factor X 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. 2nd ed. Little, Brown, and Company; 1975:143-145; Cielsa B. Defects of plasma clotting factors. In: Hematology in Practice. 3rd ed. FA Davis; 2019:chap 17)

If the inhibitor screen is positive for an inhibitor of factor X, 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 X activity is measured and compared to a control run at the same time. The difference between the factor X activity of the patient's incubation mixture and that of the control is used to calculate titer. The residual factor X activity is converted to Bethesda units: 50% residual factor X 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; Cielsa B. Defects of plasma clotting factors. In: Hematology in Practice. 3rd ed. FA Davis; 2019:chap 17)

### 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 Laboratories - Rochester Main Campus

## 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

85390
85260
85335 (if appropriate)
85335 (if appropriate)
85390 (if appropriate)

### LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---|---|---|
| 10INE | Factor X Inhib Profile, P | 96457-7 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| F_10 | Coag Factor X Assay, P | 3218-5 |
| 10INT | FX Inhib Profile Tech Interp | 69049-5 |