Test Definition: FXCH

Coagulation Factor X Chromogenic Activity Assay, Plasma

Overview

Useful For

Monitoring warfarin anticoagulant therapy, especially in patients whose plasma contains lupus anticoagulants that interfere with baseline prothrombin time/international normalized ratio and in patients receiving the drug argatroban who are being transitioned to warfarin

This assay should **not be used** for monitoring heparin or oral direct factor Xa inhibitors such as rivaroxaban (Xarelto), apixaban (Eliquis), or edoxaban (Savaysa).

Special Instructions

- Coagulation Guidelines for Specimen Handling and Processing

Method Name

Chromogenic

NY State Available

Yes

Specimen

Specimen Type

Plasma Na Cit

Ordering Guidance

If factor X deficiency is suspected, order F_10 / Coagulation Factor X Activity Assay, Plasma.

Specimen Required

Patient Preparation:

Fasting: 8 hours, preferred but not required

Collection Container/Tube: Light-blue top (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. For complete instructions see Coagulation Guidelines for Specimen Handling and Processing
2. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.
3. Aliquot plasma into a separate plastic vial leaving 0.25 mL in the bottom of the centrifuged vial.
4. Freeze plasma immediately (no longer than 4 hours after collection) at -20 degrees C or, ideally, at -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.
3. If priority specimen, mark request form, give reason, and request a call-back.

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
The antithrombotic effect of oral vitamin K antagonists (eg, warfarin) is mediated by reduction in the plasma activity of vitamin K-dependent procoagulant factors II (prothrombin) and X. The intensity of oral anticoagulation therapy with vitamin K antagonists must be monitored and adjusted to a narrow therapeutic range; undermedicating increases the risk of thrombosis, while overmedicating increases the risk of bleeding. Such therapy typically is monitored with the prothrombin time/international normalized ratio (INR) system.

Lupus anticoagulants (LAC) are autoantibodies that interfere with phospholipid-dependent clotting tests and most commonly cause prolongation of the activated partial thromboplastin time (APTT). LAC can be associated with a prothrombotic disorder termed antiphospholipid syndrome. LAC occasionally may cause prolongation of the baseline prothrombin time, rendering the INR system inaccurate for monitoring the intensity of oral anticoagulant therapy. LAC-induced prolongation of the prothrombin time is most commonly seen with recombinant human tissue factor thromboplastins (ie, prothrombin time reagents) with a low international sensitivity index (ISI) such as Innovin or RecombiPlasTin 2G (ISI = 1.0). The chromogenic factor X activity is an alternative assay for monitoring oral anticoagulant therapy. This assay is unaffected by LAC because the assay endpoint is not a phospholipid-dependent clotting time.

Argatroban is a parenteral direct thrombin inhibitor that is approved for treatment of heparin-induced thrombocytopenia (HIT), an antibody-mediated prothrombotic disorder. Argatroban therapy prolongs the prothrombin time, which also renders the INR inaccurate for monitoring the warfarin effect while transitioning from argatroban to

oral anticoagulant therapy. The chromogenic coagulation factor X activity assay may be used as an alternative to the INR for monitoring and adjusting the warfarin dose during this transition.

Reference Values
> or =18 years of age: 60%-140%

Chromogenic Factor X activity generally correlates with the one-stage factor X activity. In full term or premature neonates, infants, and children, the one-stage factor X activity* is lower than adult reference range and progressively rises to the adult reference range by adolescence. However, no similar data for the chromogenic factor X activity have been published.

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

Interpretation
A chromogenic factor X activity of approximately 20% to 40% corresponds to the usual warfarin international normalized ratio range (ie, 2.0-3.0).

Cautions
Liver disease and vitamin K deficiency may lower factor X levels.

Clinical Reference
1. Douxfils J, Ageno W, Samama CM, et al. Laboratory testing in patients treated with direct oral anticoagulants: a practical guide for clinicians. J Thromb Haemost. 2018;16(2):209-219. doi:10.1111/jth.13912
2. Kim PY, Di Giuseppantonio LR, Wu C, Douketis JD, Gross PL. An assay to measure levels of factor Xa inhibitors in blood and plasma. J Thromb Haemost. 2019;17(7):1153-1159
3. Baker P, Platton S, Gibson C, et al. Guidelines on the laboratory aspects of assays used in haemostasis and thrombosis. Br J Haematol. 2020;191(3):347-362
4. Greenmyer JR, Niaz T, Kohorst MA, Stephens EH, Anderson JH. Chromogenic factor X assay for monitoring warfarin anticoagulation in a child with a prosthetic mitral valve. Mayo Clin Proc Innov Qual Outcomes. 2021;5(5):811-816

Performance

Method Description
The chromogenic factor X assay is performed on the Instrumentation Laboratory ACL TOP. In this 2-stage assay, an incubated dilution of the patient's plasma is combined in equal volumes with a chromogenic substrate and a Russell's viper venom/calcium chloride reagent. The patient's plasma factor X is activated in the presence of calcium by the activator Russell's viper venom, which then hydrolyzes the chromogenic substrate creating 2 products, peptide and pNA (paranitroaniline). The pNA is then measured at 405 nm and is proportional to the amount of factor X in the patient's plasma.(Package insert: Diapharma Factor X Kit. DiaPharma Group, Inc.; Rev 06/2006)

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
85260

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
FXCH	Factor X Chromogenic Activity Assay	33984-6

Result ID	Test Result Name	Result LOINC® Value
FXCH	Factor X Chromogenic Activity Assay	33984-6