Lab Dept: Coagulation

Test Name: FACTOR IX ASSAY, CHROMOGENIC

General Information

Lab Order Codes:	F9C
Synonyms:	Hemophilia B; Christmas Disease; Auto-prothrombin II; Plasma Thromboplastin Component; PTC; Factor IX Activity
CPT Codes:	85130 – Factor IX Chromogenic
Test Includes:	Factor IX level reported as % using the chromogenic method.

Logistics

Test Indications:	Useful for the detection of single factor congenital homozygous or heterozygous deficiency or acquired due to Vitamin K deficiency or liver disease. Typically, these patients would be tested using the 1-stage clotting assay. However new treatment options (i.e. glycoPEGylated replacement products) are being approved for clinical use. Pharmacokinetic studies for these products indicate ideal monitoring of patients should be performed by the 2-stage chromogenic assay.
Lab Testing Sections:	Coagulation
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours; testing is performed at Minneapolis location only.
Turnaround Time:	4 hours
Special Instructions:	See Patient Preparation

Specimen

Specimen Type:	Whole blood
Container:	Light Blue top (Buffered Na Citrate 3.2%) tube

Draw Volume: 1.8 mL blood (in 2 mL tube) or 2.7 mL blood (in a 3 mL tube).

Processed Volume: 0.9 ml plasma

Collection:

● A clean venipuncture is essential, avoid foaming
● Entire sample must be collected with single collection, pooling of sample is unacceptable.
● Capillary collection is unacceptable.
● Patient's with a hematocrit level >55% must have a special tube made to adjust for the hematocrit; contact lab for a special tube.
● Mix thoroughly by gentle inversion. Deliver immediately to the laboratory at room temperature via courier or pneumatic tube.

Off campus collections:
● Must be tested within 4 hours.
● Do not refrigerate.
● If not received in our lab within 4 hours of collection, sample must be centrifuged and "platelet-poor plasma removed from cells and transferred to an aliquot tube being careful not to distribute to disturb the cell layer. Centrifuge the plasma a second time and transfer into a clean aliquot tube being careful not to include any residual platelets on the bottom of the tube. Freeze at -20 degrees C and deliver to the lab on dry ice within 2 weeks.
***Validation of your lab's centrifuge for platelet poor plasma is required.**

Special Processing: Lab staff: Centrifuge in Stat Spin for 5 minutes or 10 minutes at 3000 rpm at room temperature. For primary tube testing, leave plasma on cells OR remove plasma and place in a 4 mL plastic cup; allow for 100 mL of dead-space.

Patient Preparation: The patient should not be receiving any of the following anticoagulant medication:

-Heparin
-Warfarin/Coumadin
-Direct thrombin inhibitor: Pradaxa (dabigatran), Acova (argatroban) -Direct Xa inhibitor: Xarelto (rivaroxaban), Eliquis (apixaban)

Sample Rejection: Improper tube; clotted samples; under-filled tube; mislabeled or unlabeled specimens.

Interpretive

Reference Range:

Age	**Range (%)**
0 - 1 day	34 - 72
2 - 5 days	34 - 72

6 – 30 days	36 - 66
31 – 90 days	44 - 90
91 – 180 days	61 - 111
6 months – 5 years	47 - 104
6 years – 10 years	63 - 89
11 – 16 years	82 - 122
>16 years	55 - 165

Critical Values: N/A

Limitations: See Patient Preparation

Methodology: Factor IX in the sample is activated by human XIa and where formed FIXa activates human FX in the presence of human FVIII, calcium ions and phospholipid. Factor VIII is activated by thrombin which is generated during the incubation. The amount of FXa formed is related to the FIX activity and is determined by the hydrolysis of a chromogenic FXa substrate. The FIX activity of the sample is assigned vs. a FIX plasma or FIX concentrate standard with FIX potency expressed in international units (IU).

Contraindications: Patient receiving anticoagulant therapy.

References: Rossix Chromogenic Factor IX product insert, ROX FACTOR IX – 90 00 20, Rossix AB SE-431 53 Molndal, Sweden Revision 04/2014

The Value of the Chromogenic Activity Assay in Diagnosis and Therapeutic Monitoring of Hemophilia, Adcock, Dorothy, Tiefenbacher, Stefan, Pruthi, Rajiv, Medical Laboratory Observer,1/27/2017

Updates: 7/18/23: Updated processing within the lab section. Added testing is only performed at the Minneapolis campus.