Lab Dept: Coagulation

Test Name: FACTOR IX ASSAY, CHROMOGENIC

General Information

Lab Order Codes:	F9C
Synonyms:	Hemophilia B; Christmas Disease; Autoprothrombin 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 (Performed on Minneapolis Campus)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
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:	2.7 ml blood

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: Spin sample collected in blue top tube(s) for 5 minutes on the Stat Spin centrifuge, remove plasma and transfer to a 4 mL BCS sample cup(s), spin remaining plasma again for 5 minutes in the Stat Spin centrifuge. Transfer plasma to new BCS sample cup(s) for analysis (as specifically stated in each procedure) leaving approximately 200 mcL in the bottom of the original cup to discard.

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; underfilled 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: 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).

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