MAYO CLINIC
Mayo Medical Laboratories

TEST ID: CH9

CHROMOGENIC FACTOR IX ACTIVITY ASSAY, PLASMA

USEFUL FOR

- Monitoring coagulation factor replacement therapy of selected extended half-life coagulation factor replacements
- Aiding in the diagnosis of hemophilia B using a 2-stage assay, especially when a 1-stage assay was normal

CLINICAL INFORMATION

Factor IX (FIX) is a vitamin K-dependent serine protease synthesized in the liver and participates in the intrinsic coagulation pathway. Its biological half-life is 18 to 24 hours.

Congenital FIX deficiency is inherited as an X-linked recessive bleeding disorder (hemophilia B). Severe deficiency (<1%) characterized by hemarthroses, deep tissue bleeding, excessive bleeding with trauma, and ecchymoses.

Typically, these patients are tested using a 1-stage clotting assay. However, new treatment options using long-acting 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.

REFERENCE VALUES

65–140%

Chromogenic Factor IX activity generally correlates with the one-stage FIX activity. In full term/premature neonates, infants, children, and adolescents the one-stage FIX activity* is similar to adults. However, no similar data for chromogenic FIX activity are available. (Appel JTH 2012; 10:2254)

*See **Pediatric Hemostasis References** in **Coagulation Studies** in Special Instructions.

ANALYTIC TIME

1 day

SPECIMEN REQUIRED

Type
Plasma Na Cit

Collection Container/Tube
Light-blue top (citrate)

Submission Container/Tube
Polypropylene vial

Specimen Volume
1 mL

01/2018

INTERPRETATION

Factor IX deficiency may be acquired (eg, vitamin K deficiency, warfarin anticoagulation effect, liver disease, or a consumptive coagulopathy) or congenital (hemophilia B).

Optimal laboratory monitoring of selected extended half-life factor IX replacement therapy (eg, glycoPEGylated factor FIX) may be achieved with the chromogenic factor IX assay. Elevated factor IX levels may be associated with acute or chronic inflammation, excess factor IX replacement therapy, or rarely, as a result of rare genetic mutation factor IX Padua.

CLINICAL REFERENCE

1. Bowyer AE, Hillarp A, Ezban M, et al: Measuring factor IX activity of noacog beta pegol with commercially available one-stage clotting and chromogenic assay kits: a two-center study. J Thromb Haemost 2016 Jul;14(7 1428-1435 doi: 10.1111/jth.13348
2. Kitchen S, Signer-Romero K, Key NS: Current laboratory practices in the diagnosis and management of haemophilia: a global assessment. Haemophilia 2015 Jul;21(4)550-557
3. Sorensen MH, Anderson S, Ezban M: Factor IX-deficient plasma spiked with N9-GP behaves similarly to N9-GP post-administration clinical samples in N9-GP ELISA and FIX activity assays. Haemophilia 2015 Nov;21(6):832-836
4. Dodt J, Hubbard AR, Wicks SJ, et al: Potency determination of factor VIII and factor IX for new product labelling and postinfusion testing: challenges for caregivers and regulators. Haemophilia 2015 Jul;21(4):543-549
5. Wilmot HV, Hogwood J, Gray E: Recombinant factor IX: discrepancies between one-stage clotting and chromogenic assays. Haemophilia 2014 Nov;20(6):891-897