MAYO CLINIC
Mayo Medical Laboratories

TEST ID: CH8

CHROMOGENIC FACTOR VIII ACTIVITY ASSAY, PLASMA

USEFUL FOR

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

CLINICAL INFORMATION

Factor VIII (FVIII) is synthesized in the endothelial cells of the liver, and perhaps in other tissues. It is a coagulation cofactor that circulates bound to von Willebrand factor and is part of the intrinsic coagulation pathway. The biological half-life is 9 to 18 hours (average is 12 hours).

Congenital FVIII deficiency results in hemophilia A, which has an incidence of 1 in 10,000 live male births, and is inherited in a recessive X-linked manner. Patients with severe deficiency (<1%) experience spontaneous bleeding episodes (eg, hemarthrosis, deep-tissue bleeding, etc), whereas patients with moderate or mild deficiency (>1%) typically experience posttrauma or surgical bleeding.

FVIII activity assays (FVIII:C) are performed to diagnose hemophilia A and to monitor FVIII replacement therapy. FVIII:C assays are typically 1-stage clotting assays. However, there is a subset of mild hemophilia A patients who have shown discrepantly low results when measured with the 2-stage (chromogenic) assay, indicating that testing patients with a mild bleeding history with both a 1- and 2-stage assay would aid in diagnosis. In addition, there are new treatment options using long-acting glycoPEGylated products. Pharmacokinetic studies are showing that ideal monitoring of patients should be performed by the 2-stage chromogenic assay.

REFERENCE VALUES

55–200%

Chromogenic Factor VIII activity generally correlates with the one-stage FVIII activity. In full term/premature neonates, infants, children, and adolescents the one-stage FVIII activity* is similar to adults. However, no similar data for chromogenic FVIII 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 VIII deficiency may be seen in congenital hemophilia A, acquired (autoimmune) hemophilia A, or von Willebrand disease (congenital and acquired). Laboratory artifacts that may result in artificially reduced factor VIII include samples collected in EDTA, instead of citrate, or heparin contamination of the plasma sample.

Elevated factor VIII may be seen in acute or chronic inflammatory states, or excess factor VIII replacement therapy.

CLINICAL REFERENCE

1. Rodgers SE, Duncan EM, Sobieraj-Teague M, Lloyd JV: Evaluation of three automated chromogenic FVIII kits for the diagnosis of mild discrepant haemophilia A. Int J Lab Hematol 2009;31(2):180-188
2. Kitchen S, Beckman H, Katterle Y, et al: BAY 81-8973, a full-length recombinant factor VIII: results from an International comparative laboratory field study. Haemophilia 2016 May;22(3):e192-199 doi: 10.1111/hae.12925
3. Peyvandi F, Oldenburg J, Friedman KD: A critical appraisal of one-stage and chromogenic assays of factor VIII activity. J Thromb Haemost 2016 Feb;14(2):248-261
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