Factor VIII Chromogenic (Activity and Inhibitor)

Versiti's Factor VIII activity by chromogenic method is recommended for measuring endogenous or infused factor VIII activity. This assay uses bovine reagents and is not affected by the presence of emicizumab-kxwh.

Versiti's Factor VIII inhibitor by chromogenic method is recommended to determine the presence of factor VIII inhibitor in patients with hemophilia A or acquired hemophilia, including patients receiving non-replacement products such as emicizumab-kxwh.

Hemophilia A is an X-linked inherited bleeding disorder caused by mutation of the factor VIII (F8) gene that encodes for coagulation factor VIII. Diagnosis and monitoring of therapy for patients receiving factor VIII replacement therapy is accomplished via either clot based (one-stage) or chromogenic factor VIII assay. Selection of assay method is guided by both the clinical question being addressed and the treatment that a hemophilia patient is receiving.

Acquired hemophilia is an immune disorder due to formation of auto-antibody to factor VIII. It may occur as a complication of other autoimmune diseases, pregnancy, lymphoproliferative disorders, monoclonal gammopathies, or advanced age.

Indications for testing:

Factor VIII Activity - Chromogenic is recommended for diagnostic evaluation of patients with suspicion of hemophilia A. For patients undergoing evaluation for mild hemophilia A in whom there may be a discrepancy between one-stage and chromogenic factor VIII activity, it is recommended that both assays be performed.

Factor VIII Inhibitor by chromogenic method is recommended for the monitoring of patients with hemophilia A receiving either standard or extended half-life factor VIII products, for evaluation of patients who become refractory to factor VIII replacement therapy, for monitoring patients on immune tolerance induction, and for diagnosis or monitoring inhibitor titers in patients with acquired hemophilia A. Because this assay uses bovine reagents, it can also be used for monitoring of residual factor VIII levels in patients receiving emicizumab-kxwh.

Test method:

Chromogenic using bovine reagents

Assay sensitivity and limitations:

Factor VIII activity by chromogenic method is adversely affected by presence of heparin-based anticoagulant medications (unfractionated heparin, low molecular weight heparin, fondaparinux) and direct factor Xa inhibitors (rivaroxaban, apixaban, edoxaban). It is relatively insensitive to lupus anticoagulant.

Factor VIII may be elevated in patients with acute phase reaction or pregnancy. Assay results are not affected by the presence of emicizumab-kxwh. This chromogenic assay is not accurate for measurement of either recombinant porcine factor VIII activity or measurement of porcine factor VIII inhibitor. For evaluation of porcine Factor VIII please refer to test code 1086: Porcine Factor VIII Inhibitor Profile.

Reporting of Results

Factor VIII Activity (Test Code(s): 1135, 1136): Reportable range: approximately 1-600 IU/dL.

Factor VIII Inhibitor (Test Code(s): 1137, 1138): Reportable range: 0.3 – 4000.0 BU

versiti™

Specimen requirements:

Factor VIII Activity (1135): Two 0.5 ml aliquots, citrated plasma (light blue top), frozen. (Minimum volume: two 0.4 mL aliquots.)

Factor VIII Activity – Hepzyme Treated (1136): Two 0.6 ml aliquots, citrated plasma (light blue top), frozen. (Minimum volume: two 0.6 mL aliquots.)

Factor VIII Inhibitor (1137): 1.5 mL Citrated Plasma (light blue top) Frozen. (Minimum Volume: 1mL)

Factor VIII Inhibitor – Hepzyme Treated (1138): 2 mL Citrated Plasma (light blue top) Frozen. (Minimum Volume: 1.5 mL)

SHIP

Shipping requirements:

Place the frozen specimen and the requisition into plastic bags, seal and place in an insulated container. Surround with at least 5 pounds of dry ice. Seal the insulated container, place into a sturdy cardboard box, and tape securely. Ship the package in compliance with your overnight carrier guidelines. Address package to:

Versiti Client Services/Hemostasis Reference Laboratory
638 N. 18th St.
Milwaukee, WI 53233

ORDER

Required forms:

Please complete all pages of the requisition form.

CPT Codes/Billing/Turnaround time:

Test Code:

1135 - Factor VIII Activity – Chromogenic

1136 - Factor VIII Activity Hepzyme Treated - Chromogenic

1137 - Factor VIII Inhibitor

1138 - Factor VIII Inhibitor - Hepzyme Treated

CPT codes:

85130 – Factor VIII Activity – Chromogenic

85130, 85525 – Factor VIII Activity Hepzyme Treated – Chromogenic

85335 – Factor VIII Inhibitor

85335, 85525 Factor VIII Inhibitor – Hepzyme Treated

Turnaround time: Test Code(s): 1135, 1136: 5 days

Test Code(s): 1137, 1138: 7 days

References:

1. Peyvandi F, Oldenburg J, Friedman KD. A critical appraisal of one-stage and chromogenic assays of factor VIII activity. J Thromb Haemost. 2016; 14(2):248-261.
2. Tripodi A, Chantarangkul V, Novembrino C, Peyvandi F. Advances in the Treatment of Hemophilia: Implications for Laboratory Testing. Clin Chem. 2019; 65(2): 254-262.

versiti™