Porcine FVIII Inhibitor Profile

Versiti offers testing for coagulation inhibitors that react with recombinant porcine sequence factor VIII.

Acquired hemophilia A is a rare acquired bleeding disorder due to formation of autoantibodies to coagulation factor VIII (FVIII). Confirmation of a diagnosis involves demonstrating a low FVIII level and presence of an inhibitor to FVIII by Bethesda assay. Until recently, therapy of bleeding symptoms involved either overwhelming the inhibitory antibody with human FVIII concentrate, or bypassing the need for FVIII with either recombinant Factor VIIa or activated prothrombin complex concentrate. Recombinant B-domaindeleted porcine factor VIII (rpFVIII, OBIZUR®, Baxalta), has been licensed as a potential alternative therapy for bleeding in these patients. However, FVIII autoantibodies may cross-react with rpFVIII and patients receiving porcine FVIII therapy may produce anti-porcine FVIII inhibitors following treatment with that product. The Porcine Factor VIII Inhibitor Profile is useful to detect and quantify porcine FVIII Inhibitors and may help guide treatment.

Hemophilia A (congenital Factor VIII deficiency) is an X-linked inherited bleeding disorder caused by a defective F8 gene. While therapeutics containing human recombinant FVIII (rFVIII) are a mainstay of therapy for treating patients with congenital hemophilia A, roughly 15% of patients receiving FVIII therapy develop an inhibitor. Therapy of bleeding after inhibitor formation is similar to that of acquired hemophilia A mentioned above.

Indications for testing:

Assess titer of inhibitory activity to recombinant porcine factor VIII in patients where OBIZUR® therapy is being considered for the treatment of bleeding, or when OBIZUR® has been previously administered.

Test method:

Clotting Bethesda Titer.

Assay sensitivity and limitations:

- Heparin contamination may interfere with inhibitor quantification.
- Very high titer lupus anticoagulant may interfere with accurate inhibitor titer assessment.
- Recent FVIII (or rpFVIII) infusion may increase clearance of an inhibitor, resulting in reduction of the observed inhibitor titer.
- Samples obtained from patients receiving emicizumab therapy will exhibit elevated FVIII levels so the inhibitor assay cannot be performed.

Specimen requirements:

2 - 1 ml aliqouts Citrated Plasma (light blue top) shipped frozen.

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. Send to:

Versiti Client Services
Hemostasis Reference Laboratory
638 N. 18th Street
Milwaukee, WI 53233
800-245-3117, ext. 6250

versiti™

ORDER

Required forms:

Please complete all pages of the requisition form.

CPT Codes/Billing/Turnaround time:

Test code:
1084 – Porcine Factor VIII Inhibitor Profile – Hepzyme Treated
1086 – Porcine Factor VIII Inhibitor Profile

For suggested CPT codes, visit the Versiti.org/test menu

Turnaround time: 7 days

References:

1. Kruse-Jarres R, St-Louis J, Greist A, et al. Efficacy and safety of OBI-1, an antihaemophilic factor VIII (recombinant), porcine sequence, in subjects with acquired haemophilia A. Haemophilia 2015; 21:162-170.

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