Overview

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

Testing Algorithm
This assay is indicated in situations where there is a clinical suspicion of hemophilia A diagnosis, but the 1-stage Factor VIII assay is normal. However, recent guidelines also recommend this assay be performed in addition to the 1-stage assay in the initial workup of hemophilia A.

Testing for autoantibodies to FVIII in the presence of a low FVIII activity may be clinically indicated. For adding on FVIII inhibitor, contact Mayo Clinic Laboratories within 7 days to assess if adequate plasma sample is available.

Coagulation testing is highly complex, often requiring the performance of multiple assays and correlation with clinical information. For that reason, we recommend requesting a coagulation consultation.

See Hemophilia Testing Algorithm in Special Instructions.

Special Instructions
- Coagulation Guidelines for Specimen Handling and Processing
- Hemophilia Testing Algorithm

Method Name
Chromogenic

NY State Available
Yes

Specimen

Specimen Type
Plasma Na Cit

Necessary Information
If a priority specimen, mark request form, give reason, and request a call-back.

Specimen Required
See Coagulation Guidelines for Specimen Handling and Processing in Special Instructions.

Specimen Type: Platelet-poor plasma

Collection Container/Tube: Light-blue top (citrate)

Submission Container/Tube: Polypropylene vial

Specimen Volume: 1 mL
Collection Instructions:

1. Centrifuge, remove plasma, and centrifuge plasma again.
2. Freeze specimen immediately at < or =-40 degrees C, if possible.
3. Freeze within 4 hours of collection.

Additional Information:

1. Double-centrifuged specimen is critical for accurate results as platelet contamination may cause spurious results.
2. Each coagulation assay requested should have its own vial.

Forms

If not ordering electronically, complete, print, and send a Coagulation Test Request (T753) with the specimen.

Specimen Minimum Volume

0.5 mL

Reject Due To

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<td>Gross icterus</td>
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Specimen Stability Information

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<tr>
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Clinical and Interpretive

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 section in Coagulation Guidelines for Specimen Handling and Processing in Special Instructions.

**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.

**Cautions**

Excess heparin and dilution contamination due to improper specimen collection through an intravenous access device may result in artifically decreased results.

The 1-stage and chromogenic factor VIII (FVIII) assay results should correlate in the normal population, but may be discordant in the hemophilia population and when measuring FVIII replacement.

**Clinical Reference**


**Performance**

**Method Description**

The Chromogenic Factor VIII assay is performed on the Instrumentation Laboratory ACL TOP 700 using the Chromogenix Coatest SP FVIII kit. In this 2-stage assay, patient plasma is diluted and combined with reagents containing factors IXa and X, calcium, and phospholipids. The factor VIII in the patient's plasma aids in the activation of factor X to factor Xa. After a specified incubation period, chromogenic substrate is added at which time, the factor Xa, present from the previous step, hydrolyzes the substrate into peptide and pNA. The color produced by the release of pNA is measured photometrically at 405 nm and is proportional to the factor VIII in the sample.(Package insert: Chromogenix COATEST SP FVIII kit. Instrumentation Laboratory Company, Beford, MA, R3 02/2015)
PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
7 days

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been modified from the manufacturer’s instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
85130

LOINC® Information

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