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 result 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 (FVIII) assay result is normal. However, recent guidelines 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, call 800-533-1710 within 7 days to assess if adequate plasma sample is available.

For more information see Hemophilia Testing Algorithm

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

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

Specimen Required
Specimen Type: Platelet-poor plasma
Collection Container/Tube: Light-blue top (3.2% sodium citrate)
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions:
1. Specimen must be collected prior to factor replacement therapy.
2. For complete instructions, see Coagulation Guidelines for Specimen Handling and Processing
3. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.
4. Aliquot plasma into plastic vial leaving 0.25 mL in the bottom of centrifuged vial.
5. Freeze plasma immediately (no longer than 4 hours after collection) at -20 degrees C or, ideally, below -40 degrees C.

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>IV heparin</td>
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Specimen Stability Information

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Clinical & 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 is inherited in a recessive X-linked manner and results in hemophilia A, which has an incidence of 1 in 10,000 live male births. Patients with severe deficiency (<1%) experience spontaneous bleeding episodes (e.g., hemarthrosis, deep-tissue bleeding), whereas patients with moderate or mild deficiency (>1%) typically experience post-trauma 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 patients with mild hemophilia A 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**

55.0-200.0%

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 IM, Grimminck B, Geerts J, Stigter R, Cnossen MH, Beishuizen A. Age dependency of coagulation parameters during childhood and puberty. J Thromb Haemost. 2012 Nov;10(11):2254-63)

*See Pediatric Hemostasis References section in Coagulation Guidelines for Specimen Handling and Processing

**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 artifactually 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 Family using the CRYOcheck Chromogenic Factor VIII kit. In this 2-stage assay, patient plasma is diluted and combined with reagents containing...
bovine factor X, human factors IXa and IIa, calcium chloride, 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 p-nitroaniline (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: CRYOcheck Chromogenic Factor VIII. Precision BioLogic Inc; Rev V04 06/2020)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
1 to 3 days

Specimen Retention Time
7 days

Performing Laboratory Location
Rochester

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer’s instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
85130

LOINC® Information

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