Chromogenic Factor FVIII

Effective March 15, 2021, the Thrombosis and Hemostasis Laboratory will offer the Chromogenic FVIII Activity Assay. This assay does not replace the current clot-based, 1-stage FVIII activity assay, and in most cases, the current FVIII activity assay is appropriate. Please contact the Thrombosis and Hemostasis Laboratory should you need guidance as to which activity assay is best for your patient. Please note, this new assay is available only as a routine test, and stat testing is not available.

Clinical Application:

This 2-stage, chromogenic methodology used for measuring FVIII activity is indicated for specific clinical situations:

- Aid in the initial diagnostic evaluation of hemophilia A, particularly when the clot-based FVIII activity assay is normal
- A subset of hemophilia A patients have shown discrepantly low FVIII results when measured using the chromogenic method compared to the clot-based method. Guidelines recommend performing both the chromogenic and clot-based FVIII activity assays in the initial hemophilia A diagnostic evaluation.
- Monitoring anti-hemophiliac FVIII factor replacement therapy of selected extended half-life coagulation factor replacements
- New anti-hemophiliac treatment options using an extended half-life factor replacement is best measured using the chromogenic FVIII assay, particularly when performing pharmacokinetic studies.
- Please note, the 1-stage, clot-based and 2-stage, chromogenic FVIII assay results should correlate in the normal population, but activity results may be discordant in the hemophilia population and when measuring FVIII replacement. The chromogenic FVIII assay is insensitive to emicizumab (Hemlibra).
- If a patient is on emicizumab will impact the aPTT-based coagulation assays, as outlined in the Table, below, and the aPTT-based assays are NOT accurate in a person taking emicizumab for up to 6 months following discontinuation of the medication.

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CHROMOGENIC FACTOR VIII

Important Note

This chromogenic substrate assay (CSA) is necessary for measuring a patient's endogenous factor VIII activity or therapeutic factor VIII replacement medication, including the extended life factor replacement products.

This assay will measure these factor VIII activities and is not impacted by the new bi-specific monoclonal antibody therapy emicizumab (Hemlibra); our current one-stage assay (OSA) is a clot-based factor VIII activity assay and will overestimate a patient's endogenous or therapeutic factor VIII in the presence of emicizumab.

Finally, recent recommendations suggest using both the OSA (factor VIII) and CSA (chromogenic factor VIII) methods for the initial diagnostic investigation of Hemophilia A or where there is a clinical suspicion of Hemophilia A and yet the clotting test is normal (e.g. helpful to diagnose "Discrepant Hemophilia A").

Additional Codes

Primary ID	Epic Code	Atlas Code	Mayo Access ID	Order Code LOINC
LAB14969	LAB14969	LAB14969	FAH5939	49865-9

Result Code(s)

Reporting Name	Epic Code	Atlas Code	Mayo Access ID	LOINC
Chromogenic Factor VIII	12301012044	CHROM8R	FAH5940	49865-9

Specimen Information

Container	Specimen	Temperature	Collect Vol	Submit Vol	Min Vol	Stability
*Blue Top Tube	Plasma	Frozen	To fill line	1 mL	0.5 mL	6 months
3.5 mL Blue Top	Whole Blood	Ambient	To fill line	To fill line	To fill line	2 hours
2 mL Blue Top	Whole Blood	Ambient	To fill line	To fill line	To fill line	2 hours

*Preferred specimen type

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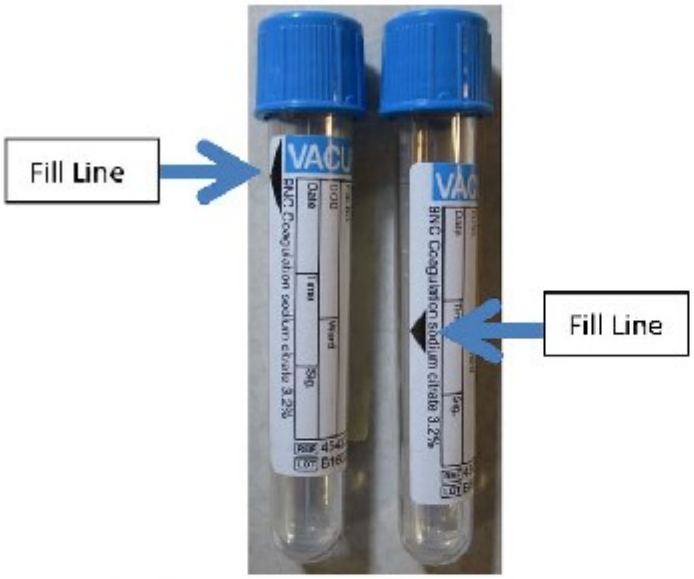
Refer to **Coagulation Specimen Handling** before collecting. Submit 2 × 0.5 mL frozen plasma aliquots for this test. Draw blood in light blue top tube(s). Spin down, remove plasma, spin plasma again, and place citrate platelet-poor plasma in required number of plastic vials (Glass vials cannot be accepted.) Freeze specimen at less than or equal to minus 40° C, if possible. Send specimen frozen on dry ice. Each coagulation assay requested should have its own vial.



Test Schedule / Analytical Time / Test Priority

Monday – Friday / 1 day / NOT available STAT

Method

Chromogenic Substrate Assay

Instrumentation

ACL TOP

Reference Range

≥ 18 years: 43.2 – 159.3%

CPT(s)

Description	CPT Code
Chromogenic Assay Coagulation Test	85130