TRICORE

COAGULATION LABORATORY
FACTOR VIII (F8) ACTIVITY ASSAY UPDATE

Effective December 15, 2020, TriCore's Special Coagulation Laboratory is pleased to introduce the next generation of F8 activity testing. The lab is transitioning from the one-stage, clot-based assay to a chromogenic assay for F8 activity testing **ONLY**. All other factor activity assays performed at TriCore will continue to be performed by clot-based methodology.

Noted below are some benefits of the assay, as well as the elimination of persistent interferences.

This chromogenic F8 activity assay **WILL** provide:

- Quantitative measurement of F8 activity from <1% to 200% (reference range = 43.2-159.3%)
- Improved characterization of mild/moderate/severe classification of Hemophilia A
- Improved measurement of in vivo levels of recombinant F8 (rF8) and F8 extended half-life products
- Ability to measure native F8, as well as plasma-derived (pdF8) and/or rF8 in the presence of Emicizumab (Hemlibra®)
- Decreased interference from hemoglobin, lipemia, icterus, unfractionated and low-molecular weight heparin (accurate up to 2 IU/mL), Fondaparinux (accurate up to 1.25 mg/L), and lupus anticoagulant

This chromogenic F8 activity assay **WILL NOT** provide:

- Accurate results in the setting of direct oral anticoagulants (DOACs) and direct thrombin inhibitors (DTIs)
- Qualitative or quantitative measurement of Emicizumab (Hemlibra®) levels

References

Potgieter, J.J., Damgaard, M. and Hillarp, A. One-stage vs. chromogenic assays in haemophilia A. Eur J Haematol. 2015; 94: 38-44.

Kitchen, S., Kershaw, G. and Tiefenbacher, S. Recombinant to modified factor VIII and factor IX – chromogenic and one-stage assays issues. Haemophilia. 2016; 22: 72-77.

Marlar, RA, Strandberg, K, Shima, M, Adcock, DM. Clinical utility and impact of the use of the chromogenic vs one-stage factor activity assays in haemophilia A and B. Eur J Haematol. 2020; 104: 3–14.

PB CRYOcheck™ Chromogenic Factor 8 kit package insert, July 2020.