

Precision BioLogic Presents New Approach to Standardize and Improve Inhibitor Testing for People with Hemophilia A

New data highlights promising performance of a new kit for use in a modified Nijmegen-Bethesda Assay

For Immediate Release

HALIFAX, March 13, 2018—Precision BioLogic, in collaboration with Roche and Genentech, a member of the Roche Group, unveiled data from the study of a new kit for a modified Nijmegen-Bethesda Assay (MNBA) at the Thrombosis & Hemostasis Societies of North America (THSNA) summit in San Diego, California last week. Recognizing the need to standardize and improve Factor VIII (FVIII) inhibitor testing for people with hemophilia A, the companies collaborated on the development of the new MNBA kit and the recent study. According to the study, the new kit shows promise for laboratories seeking a standardized inhibitor assay suitable for clinical management or multi-center clinical studies of people with hemophilia A.

The study compared FVIII inhibitor values determined using the new MNBA kit with both a chromogenic assay and a one-stage, clot-based FVIII assay. The chromogenic assay showed superior reproducibility compared to the one-stage clotting assay. In addition, the study indicated that the MNBA kit could potentially help improve the high variability in the FVIII inhibitor assay.

Based on the study results, Precision BioLogic plans to commercialize the kit and will seek clearance from regulatory authorities around the globe beginning in late 2018. The company will continue to look for other opportunities to innovate in the field of hemostasis and diagnostics.

“Precision BioLogic has been developing, manufacturing and marketing hemostasis diagnostic products for more than 25 years,” says Paul Empey, President & CEO of Precision BioLogic. “We’re excited to expand our product offerings and make a meaningful contribution that has the potential to improve the quality of life for people with hemophilia.”

In the study, the modifications to the MNBA included a heat treatment of plasma samples and substitution of FVIII deficient plasma with an albumin solution. To standardize inhibitor titer measurement, the kit was developed with the following components:

- Imidazole-buffered pooled normal plasma
- Imidazole-buffered bovine serum albumin to replace FVIII deficient plasma in the Nijmegen assay
- Positive FVIII inhibitor control
- FVIII inhibitor-free human plasma

All kit components were frozen, similar to Precision BioLogic’s line of *CRYOcheck*[™] diagnostic products, which closely resemble frozen patient samples. Frozen plasma samples from people with hemophilia A with a history of FVIII inhibitors and from normal donors were used in the study.

A poster of the study, *Performance of a New Kit for a Modified Nijmegen-Bethesda Assay: Comparison of a Chromogenic Versus a Clot-based Factor VIII Inhibitor Assay in Plasma from Persons with Hemophilia A (PwHA)*, can be downloaded from the Precision BioLogic website.

About Hemophilia A and Inhibitors

Hemophilia A is an inherited bleeding disorder caused by insufficient clotting factor VIII (FVIII) in the blood. People with hemophilia A experience prolonged bleeding, which can lead to permanent joint damage and life-threatening hemorrhages. The standard treatment for people with hemophilia A without inhibitors is intravenous (IV) FVIII replacement therapy with recombinant FVIII (rFVIII) or plasma-derived FVIII (pdFVIII) concentrates. Prophylaxis, the regular infusion of clotting factor concentrates, is used to prevent bleeds thereby minimizing joint damage.

Unfortunately, up to 30% of people with hemophilia A develop inhibitors, an immune response to treatment with clotting factor concentrates. Inhibitors make it more difficult to manage and treat hemophilia. In fact, according to the World Federation of Hemophilia, apart from access to care and treatment, inhibitors are the most serious challenge in hemophilia care today.¹ While routine blood tests may suggest the presence of inhibitors, specialized testing is important to confirm not only the presence of inhibitors but also the quantitation to effectively adjust treatment. Current methods for inhibitor testing vary from lab to lab and there is not an FDA-cleared gold standard for reference.

About Precision BioLogic

Precision BioLogic is a privately-held company that develops, manufactures and markets specialized products used by medical professionals and researchers around the globe to diagnose coagulation disorders. Precision BioLogic also has several active initiatives with pharmaceutical partners who seek to ensure that the diagnostic implications for their novel therapeutic agents have been well characterized. For more information, visit www.precisionbiologic.com.

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¹ World Federation of Hemophilia. Current issues in inhibitors. Available at <https://www.wfh.org/en/Current-issues-in-inhibitors>. Accessed on February 22, 2018.