PrecisionBioLogic

Precision BioLogic Launches Product to Improve Inhibitor Testing for People with Hemophilia A

CRYO*check*™ Factor VIII Inhibitor Kit Now Cleared for Sale in Canada, EU, Australia, and New Zealand

For Immediate Release

HALIFAX, February 11, 2019—Precision BioLogic Inc., a leading developer of hemostasis diagnostic products, is pleased to announce the availability of its new CRYO*check* Factor VIII Inhibitor Kit in Canada, the European Union, Australia, and New Zealand following market authorization by Health Canada and respective in-country regulatory authorities last month.

The presence of factor VIII (FVIII) inhibitors reduces therapy effectiveness and is one of the most complex and costly complications for people with hemophilia A. Because of this, it is important for clinical laboratories to have a testing system that can accurately and precisely quantify FVIII inhibitors in patient samples.

Precision BioLogic developed the CRYO*check* Factor VIII Inhibitor Kit to address this challenge. It contains standardized components and a validated procedure to prepare patient samples for performing a modified Nijmegen-Bethesda assay as per the U.S.-based Centers for Disease Control and Prevention (CDC) recommendation[1]. A modified Nijmegen-Bethesda assay is used to determine FVIII inhibitor levels in people with hemophilia A.

Paul Empey, President & CEO of Precision BioLogic, notes that the launch of the CRYO*check* Factor VIII Inhibitor Kit is an important step forward for patient care. “Enhancing patient care is at the core of everything we do at Precision BioLogic,” he says. “Our kit will standardize the preparation of patient samples for inhibitor titer measurement. This, in turn, will help labs deliver accurate results for the diagnosis and routine monitoring of FVIII inhibitors.”

To eliminate FVIII depleted plasma as a potential source of variant and standardize inhibitor titer measurement, the kit was developed with the following components:

- Imidazole Buffered Pooled Normal Plasma
- Imidazole Buffered Bovine Serum Albumin
- Negative FVIII Inhibitor Control
- Positive FVIII Inhibitor Control

Like all of Precision BioLogic’s CRYO*check* products, kit components are frozen, allowing for fast and easy preparation.

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Precision BioLogic has submitted the kit to the U.S. FDA for clearance and hopes to be able to offer the kit to its customers throughout the United States in Q3 2019. The company is actively pursuing other opportunities to innovate in the field of hemostasis and diagnostics.

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.[2] While routine blood tests may suggest the presence of anti-FVIII antibodies, 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.

About Precision BioLogic

Precision BioLogic Inc. is a privately-held company that develops, manufactures and markets the CRYO*check*™ line of frozen 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. In November 2018, Precision BioLogic acquired Affinity Biologicals, enabling the company to expand its clinical and research offerings to include an extensive line of coagulation-related antibodies as well as other products and services. For more information, visit www.precisionbiologic.com.

- 30 -

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[1] Miller CH, Platt SJ, Rice AS, Kelly F, Soucie JM, the Hemophilia Inhibitor Research Study Investigators. Validation of Nijmegen-Bethesda assay modifications to allow inhibitor measurement during replacement therapy and facilitate inhibitor surveillance. *J Thromb Haemost* 2012; 10: 1055–1061.

[2] World Federation of Hemophilia. Current issues in inhibitors. Available at https://www.wfh.org/en/Current-issues-in-inhibitors. Accessed on January 21, 2019.