PrecisionBioLogic

CRYO*check*™ Chromogenic Factor VIII Assay Cleared for Sale in U.S.

For Immediate Release

HALIFAX, July 20, 2020—Precision BioLogic Inc., a leading developer of hemostasis diagnostic products, is pleased to announce FDA 510(k) clearance and the launch of its new CRYO*check* Chromogenic Factor VIII assay in the U.S. This clearance follows authorizations received from regulatory authorities in Canada, the European Union, Australia, and New Zealand where the assay launched earlier this year.

CRYO*check* Chromogenic Factor VIII is intended for use by clinical labs for the determination of FVIII activity in human plasma and as an aid in the management of hemophilia A. The National Hemophilia Foundation supports the addition of cleared chromogenic assays to testing panels in clinical labs and issued a call for manufacturers to make such assays available to the U.S. market.[1]

In response to the growing demand for chromogenic assays, Precision BioLogic developed CRYO*check* Chromogenic Factor VIII to meet the needs of today's hemophilia testing laboratories. The assay is validated for use on current automated coagulation analyzers, with a test range from 0–200% FVIII using one standard curve*, and formatted to meet the needs of any size laboratory, increasing efficiency, reducing wastage and ensuring accuracy of results. Assay components are frozen, allowing for fast and easy preparation. CRYO*check* Chromogenic Factor VIII is the only commercially available, FDA-cleared chromogenic FVIII assay with a limit of quantitation below 1% that has been designed for use on automated instruments.

In August, Precision BioLogic will be hosting a free online webinar to review the benefits of chromogenic factor VIII testing and highlight the new CRYO*check* Chromogenic Factor VIII assay. To be notified of webinar details, sign up at www.precisionbiologic.com/webinar.

CRYO*check* Chromogenic Factor VIII is Precision BioLogic's second hemophilia-related product to launch recently.

"Last year we introduced a kit to help clinical laboratories accurately and precisely quantify FVIII inhibitors in patient samples," explains Paul Empey, President & CEO of Precision BioLogic. "With the launch of our latest product, we have taken a leadership role in the coagulation diagnostics industry by bringing novel, authorized solutions to clinical labs conducting hemophilia testing."

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About Hemophilia A

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 level of severity depends on the amount of clotting factor missing from a person's blood. People with severe hemophilia usually bleed frequently into their muscles or joints. They may bleed one to two times per week—often for no obvious reason. People with moderate hemophilia bleed less frequently, about once a month. They may bleed for a long time after surgery, a bad injury, or dental work. People with mild hemophilia usually bleed as a result of surgery or major injury. They do not bleed often and, in fact, some may never have a bleeding problem.

The standard treatment for people with hemophilia A 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.

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.

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* may vary based on the instrumentation in use.

[1] National Hemophilia Foundation. MASAC Document #228. MASAC Statement Regarding Use of Various Clotting Factor Assays to Monitor Factor Replacement Therapy. Available at https://www.hemophilia.org/sites/default/files/document/files/masac-228.pdf. Accessed on July 15, 2020.

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