Precision BioLogic's Chromogenic FIX Assay FDA-Cleared for Sale in U.S.

HALIFAX, January 5, 2023—Precision BioLogic Inc., a leading developer of hemostasis diagnostic products, is pleased to announce FDA 510(k) clearance and the launch of its new CRYOcheck™ Chromogenic Factor IX assay in the U.S.

The latest in Precision BioLogic's family of hemophilia-related diagnostic products, CRYOcheck Chromogenic Factor IX is intended for use by clinical labs to identify factor IX (FIX) deficiency in human plasma and aid in the management of hemophilia B. It is the only FDA-cleared chromogenic FIX assay on the market and answers a growing demand for such tests.

According to the National Hemophilia Foundation (NHF), advancements in therapies to treat hemophilia have, in some cases, revealed limitations of current one-stage clotting assays to effectively monitor replacement therapy. To address these limitations, NHF's Medical and Scientific Advisory Council recommends the addition of cleared chromogenic assays to testing panels in clinical labs.[1]

"Precision BioLogic provides tools to help laboratory professionals make the best decisions, faster," says Paul Empey, the company's President and CEO. "Recognizing the need for FDA-cleared chromogenic assays, Precision BioLogic developed CRYOcheck Chromogenic Factor IX to meet the needs of today's clinical laboratories. With the emergence of new therapies, including extended half-life FIX replacements and gene therapy, there has never been a stronger need for accurate, reliable hemophilia tests."

CRYOcheck Chromogenic Factor IX is validated for use on current automated coagulation analyzers, with a test range from 0–200% FIX activity using one standard curve*, and formatted to meet the needs of any size laboratory, increasing efficiency, reducing wastage, and ensuring accuracy of results. Like all of Precision BioLogic's products, its unique frozen format allows for fast and easy preparation.

CRYOcheck Chromogenic Factor IX launched in Canada, the EU, UK, Australia, and New Zealand in 2022. It is Precision BioLogic's second hemophilia-related chromogenic assay. In 2020, the company successfully launched its Chromogenic Factor VIII assay for the diagnosis of hemophilia A throughout North America, the EU, UK, and Australasia.

To learn more about current issues in FIX laboratory testing, join Precision BioLogic's Senior Product Manager **Ian Burns** and guest speaker **Julie Tange**, Principal Developer, Hematopathology, Special Coagulation Laboratory, Department of Laboratory Medicine, Mayo Clinic, for a free online webinar Feb. 1, 2023 at 1 pm EST. To register, visit https://register.gotowebinar.com/register/1629100627612641118.

About Hemophilia B

Hemophilia B is an inherited bleeding disorder caused by insufficient clotting factor IX in the blood. People with hemophilia B 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 B is intravenous (IV) FIX replacement therapy with recombinant FIX (including novel, extended half-life replacements), plasma-derived FIX (pdFIX) concentrates, and newly approved gene therapy. Prophylaxis, the regular infusion of clotting factor

concentrates, is used to prevent bleeds thereby minimizing joint damage. Gene therapy offers the promise of eliminating the need for FIX infusions for prophylaxis altogether.

About Precision BioLogic

Precision BioLogic Inc. is a privately-held company that develops, manufactures and markets the CRYOcheck™ 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 January 3, 2023.