Our STN: BL 125674/0

**BLA APPROVAL**
**June 14, 2019**

Abbott Ireland Diagnostics Division
Attention: Ms. Deborah Hinkley
Abbott Laboratories
Dept 09TR, Bldg. AP8A-1
100 Abbott Park Road
Abbott Park, IL 60064-6092

Dear Ms. Hinkley:

Please refer to your Biologics License Application (BLA) submitted March 29, 2018, received March 30, 2018, under section 351(a) of the Public Health Service Act (PHS Act) for Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) and Antibody to Hepatitis B Surface Antigen (Sheep).

## LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2094 to Abbott Ireland Diagnostics Division, Sligo, Ireland, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) and Antibody to Hepatitis B Surface Antigen (Sheep). Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) [Abbott Alinity s HBsAg] is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma specimens on the Alinity s System. The Abbott Alinity s HBsAg assay is intended to screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of HBsAg. The assay is also intended for use in testing serum and plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing serum specimens to screen cadaveric (non-heart-beating) donors. It is not intended for use on cord blood specimens. Antibody to Hepatitis B Surface Antigen (Sheep) [Alinity s HBsAg Confirmatory] is used to confirm the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma by means of specific antibody neutralization on the Alinity s System. The assay is intended to be used for confirmation of samples found to be repeatedly reactive by the Alinity s HBsAg assay.

Performance has not been established for the use of cadaveric blood specimens with the Alinity s HBsAg Confirmatory assay.

The review of this product was associated with the following National Clinical Trial (NCT) number: 03285295.

**MANUFACTURING LOCATIONS**

Under this license, you are approved to manufacture the Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) and Antibody to Hepatitis B Surface Antigen (Sheep) at your Abbott Ireland Diagnostics Division facility located at Finisklin Business Park, Sligo, Ireland. You may label your product with the proprietary name Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) and Antibody to Hepatitis B Surface Antigen (Sheep) and will market it as approved in your license application.

**ADVISORY COMMITTEE**

We did not refer your application to the Blood Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

**DATING PERIOD**

The dating period for Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) and Antibody to Hepatitis B Surface Antigen (Sheep) kits shall be 12 months from the date of manufacture when stored at the appropriate temperatures indicated for each component. The date of manufacture shall be defined in accordance with 21 CFR 610.50.

**FDA LOT RELEASE**

Please submit final container samples of the product Abbott Alinity s HBsAg assay and Abbott Alinity s HBsAg Confirmatory assay and each kit component in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research.

**BIOLOGICAL PRODUCT DEVIATIONS**

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

**MANUFACTURING CHANGES**

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of the Antibody to Hepatitis B Surface Antigen (Mouse Monoclonal IgG and IgM) and Antibody to Hepatitis B Surface Antigen (Sheep), or in the manufacturing facilities.

**LABELING**

We hereby approve the draft package insert labeling submitted in amendment 28, dated June 14, 2019, and the draft carton and container labeling submitted under amendment 28, dated June 14, 2019. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website at http://www.fda.gov/udi.

Please submit all final printed labeling as a PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

**ADVERSE EVENT REPORTING**

You must submit adverse experience reports in accordance with the Medical Device Reporting (MDR) requirements for medical devices (21 CFR 803) as required by 21 CFR 600.80(k)(2). Because your product is characterized as a device as well as a biologic, submit these reports to the MedWatch System using MedWatch Reporting Form 3500A or an electronic equivalent. Please refer to the *Questions and Answers about eMDR – Electronic Medical Device Reporting – Guidance for Industry, User Facilities and FDA Staff* at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm175805.htm.

Required reports are to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR Policy Branch
10903 New Hampshire Avenue
WO Bldg. 66, Room 3217
Silver Spring, MD 20993-0002

Sincerely,

Nicole Verdun, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research