



Our STN: BL 125681/0

**BLA APPROVAL  
August 2, 2019**

Abbott GmbH & Co. KG  
Attention: Ms. Deborah Hinkley  
Abbott Laboratories  
Dept. 09TR, Bldg. AP8A  
100 Abbott Park Road  
Abbott Park, IL 60064-6092

Dear Ms. Hinkley:

Please refer to your Biologics License Application (BLA) submitted May 31, 2018, received June 1, 2018, under section 351(a) of the Public Health Service Act (PHS Act) for Hepatitis B Virus Core Antigen (*E coli*, Recombinant).

## **LICENSING**

We have approved your BLA for the Hepatitis B Virus Core Antigen (*E coli*, Recombinant) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, the Hepatitis B Virus Core Antigen (*E coli*, Recombinant) under your existing Department of Health and Human Services U.S. License No. 2095. The Alinity s Anti-HBc assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of antibody to hepatitis B core antigen (anti-HBc) in human serum and plasma specimens on the Alinity s System.

The Alinity s Anti-HBc 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 anti-HBc. 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.

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 Hepatitis B Virus Core Antigen (*E coli*, Recombinant) at your facility located at Abbott GmbH & Co. KG at Max-Planck-Ring 2 in Wiesbaden, Germany. You may label your product with the proprietary name Hepatitis B Virus Core Antigen (*E coli*, Recombinant) and 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 Hepatitis B Virus Core Antigen (*E coli*, Recombinant) 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 Anti-HBc 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 (CBER).

## **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 Hepatitis B Virus Core Antigen (*E coli*, Recombinant) or in the manufacturing facilities.

## **LABELING**

We hereby approve the draft package insert labeling, carton and container labeling submitted under amendment #8, dated July 12, 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  
Office Director  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research