Our STN: BL 125802/0

BLA APPROVAL
February 21, 2024

Roche Diagnostics
Attention: Kelly Brennan
9115 Hague Road
Indianapolis, IN 46250

Dear Kelly Brennan:

Please refer to your Biologics License Application (BLA) received April 24, 2023, submitted under section 351(a) of the Public Health Service Act (PHS Act) for Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm.

LICENSING

We have approved your BLA for Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm under your existing Department of Health and Human Services U.S. License No. 2305.

Elecsys HBsAg II is an in vitro immunoassay intended for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum and plasma. Elecsys HBsAg II is intended to screen individual human donors, including volunteer donors of whole blood, blood components and source plasma. The assay is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use with **cobas pro** serology solution equipped with **cobas e** 801 analytical unit.

Elecsys HBsAg II Auto Confirm is an in vitro immunoassay for the qualitative confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum and plasma samples repeatedly reactive when tested with the Elecsys HBsAg II assay. Elecsys HBsAg II Auto Confirm is intended to confirm HBsAg presence in individual human donors, including volunteer donors of whole blood, blood components and source plasma.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use with **cobas pro** serology solution equipped with **cobas e** 801 analytical unit.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Elecsys HBsAg II at your facilities located at (b) (4) Manheim, Germany. You may label your product with the proprietary name Elecsys HBsAg II 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 Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm shall be up to the expiration date when unopened from the date of manufacture when stored at 2-8 °C or for 16 weeks when stored on-board at 2-8 °C. The date of manufacture shall be defined in accordance with 21 CFR 610.50.

FDA LOT RELEASE

Blind-coded panels will be provided for confirming lot release testing performed at Roche Diagnostics. The results of the coded samples will be forwarded to the Division of Biological Standards and Quality Control (DBSQC) through the Center for Biological Evaluation and Review (CBER) Sample Custodian as a component of the Lot Release Protocol. You may not distribute any lots of product until you receive a notification of release from the Director, 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, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations :

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 Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm, or in the manufacturing facilities.

LABELING

We hereby approve the draft package insert labeling and carton and container labeling submitted under amendment # 16 dated February 16, 2024. 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(m)(2). Because your product is characterized as a device as well as a biologic, submit these reports, listing device product code QHM, 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,

Anne Eder, MD, PhD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research