May 3, 2018

Our STN: BL 125652/0 **BLA APPROVAL**

Grifols Diagnostic Solutions, Inc.
Attention: Ms. Amanda Doe
10210 Genetic Center Drive
San Diego, CA 92121

Dear Ms. Doe:

Please refer to your Biologics License Application (BLA) for the Procleix® Ultrio Elite Assay on the Panther System dated January 26, 2017, received January 26, 2017, and submitted under section 351 of the Public Health Service Act (PHS Act).

LICENSING

We have approved your BLA for the Procleix® Ultrio Elite Assay effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, the Procleix® Ultrio EliteAssay under your existing Department of Health and Human Services U.S. License No. 2032. The Procleix® Ultrio Elite Assay is a qualitative in vitro nucleic acid amplification test to screen for human immunodeficiency virus type 1 (HIV-1), hepatitis C virus (HCV) RNA, and/or hepatitis B virus (HBV) DNA and to detect human immunodeficiency virus type 2 (HIV-2) RNA, in plasma and serum specimens from individual human donors, including donors of whole blood, blood components, and source plasma, and from other living donors. It is also intended for use in testing plasma and serum specimens to screen organ and tissue donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens from cadaveric (non-heart-beating) donors. This assay is not intended for use on cord blood specimens.

It is also intended for use in testing pools of human plasma and pools of human serum composed of equal aliquots of not more than 16 individual specimens from donors of whole blood, blood components, hematopoietic stem/progenitor cells sourced from bone marrow, peripheral blood or cord blood, and from donors of donor lymphocytes for infusion. It is also intended for use in testing pools of human plasma composed of equal aliquots of not more than 96 individual donations from donors of source plasma. Plasma and serum specimens from other living donors and from cadaveric (non-heart-beating) donors must be tested using the individul donor testing method only. This assay is intended to be used in conjunction with licensed tests for detecting antibodies to HIV-1, HIV-2, HCV, and hepatitis B core antigen, and with licensed tests for hepatitis B surface antigen (HBsAg).

This assay is not intended for use as an aid in diagnosis of infection with HIV-1, HIV-2, HCV or HBV.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture the Procleix® Ultrio Elite Assay at your facilities located at (b) (4) You may label your product with the proprietary name Procleix® Ultrio Elite Assay and market it as approved in your license application.

We did not refer your application to the Blood Products Advisory Committee because our review of the 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 the Procleix® Ultrio Elite® Assay shall be twenty-four months from the date of manufacture when stored at the appropriate temperature indicated for each component. 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 Grifols. 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, 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 Procleix® Ultrio Elite® Assay, or in the manufacturing facilities.

LABELING

We hereby approve the draft package insert labeling submitted under 125652/amendment 21 dated May 3, 2018. 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, http://www.fda.gov/udi.

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). Since 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 February 2014 document *Questions and Answers about eMDR – Electronic Medical Device Reporting – Guidance for Industry, User Facilities and FDA Staff* at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR–ElectronicMedicalDeviceReporting/UCM2019327.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
Acting Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research