May 30, 2018

Our STN: BL 125658/0 **BLA APPROVAL**

National Genetics Institute
Attention: Ms. Geri Cox
2440 South Sepulveda Boulevard, Suite 235
Los Angeles, CA 90064-1748

Dear Ms. Cox:

Please refer to your Biologics License Application (BLA) for the UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV dated May 5, 2017, received May 8, 2017, and submitted under section 351(a) of the Public Health Service Act (PHS Act).

LICENSING

We have approved your BLA for the UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, the UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV under your existing Department of Health and Human Services U.S. License No. 1582. The UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV is to screen pooled source plasma in conjunction with NGI's pooling and testing algorithm. The assay simultaneously detects HCV RNA, HIV-1 RNA (including Group M and Group O), HIV-2 RNA, and HBV DNA. This assay discriminates between HCV, HIV-1, HIV-2 and HBV positive samples but will not discriminate between HIV-1 Group M and Group O positive samples. The UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV is an "in-house" test performed only by National Genetics Institute.

MANUFACTURING LOCATIONS

Under this license, you are approved to provide results of the UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV at your facilities located at the National Genetics Institute at 2440 S. Sepulveda Boulevard, Los Angeles, California. You may label your product with the proprietary name UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV.

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.

FDA LOT RELEASE

Blind-coded panels will be provided for confirming lot release testing performed at NGI. 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 perform tests with 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, and storage. If the deviation 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 UltraQual® Multiplex PCR Assay for HCV, HIV-1, HIV-2 and HBV, or in the manufacturing facilities.

LABELING

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