

October 20, 2016

Our STN: BL 125576/0

**BLA APPROVAL**

Roche Molecular Systems, Inc.  
Attention: Ms. Angela Tucker  
4300 Hacienda Drive  
Pleasanton, CA 94588

Dear Ms. Tucker:

Please refer to your Biologics License Application (BLA) for Multiplex HIV, HCV, and HBV nucleic acid test for use on the cobas® 6800/8800 Systems dated November 12, 2014, received November 13, 2014, submitted under section 351(a) of the Public Health Service Act (PHS Act).

We have approved your BLA for Multiplex HIV, HCV, and HBV nucleic acid test for use on the cobas® 6800/8800 Systems effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, the Multiplex HIV, HCV, and HBV nucleic acid test for use on the cobas® 6800/8800 Systems under your existing Department of Health and Human Services U.S. License No. 1636. The Multiplex HIV, HCV, and HBV nucleic acid test for use on the cobas® 6800/8800 Systems is indicated for qualitative in vitro nucleic acid test for the direct detection of HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, HBV DNA in human plasma and serum.

Under this license, you are approved to manufacture the Multiplex HIV, HCV, and HBV nucleic acid test for use on the cobas® 6800/8800 Systems at your facility located at (b) (4) . You may label your product with the proprietary name cobas® MPX and will market it as approved in your license application.

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

## **DATING PERIOD**

The dating period for the Multiplex HIV, HCV, and HBV nucleic acid test for use on the cobas® 6800/8800 Systems shall be 24 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 RMS. The results of the coded samples will be forwarded to 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 this nucleic acid test for use on the cobas® 6800/8800 Systems, or in the manufacturing facilities.

### **LABELING**

We hereby approve the draft package insert labeling submitted under amendment 13, dated October 5, 2016, and the draft carton and container labeling submitted under amendment 0, dated November 13, 2014. 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>.

Please submit all final printed labeling at the time of use and include implementation information on Form FDA 356h as appropriate. Please provide a PDF electronic copy (eCopy) as well as two original paper copies for circulars and other labels.

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,

Jay S. Epstein, MD  
Director  
Office of Blood Research and Review