U.S. FOOD & DRUG ADMINISTRATION

SUPPLEMENT APPROVAL

Roche Molecular Systems, Inc.
Attention: Mr. Adam Clark
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Dear Mr. Clark:

We have approved your request dated August 11, 2017, to supplement your Biologics License Applications to add limited supplemental claims to confirm HIV, HCV, or HBV infection for speciments that are repeatedly reactive on licensed donor screening tests for antibodies to HIV, HCV, or HBsAg and reactive on the cobas® TaqScreen MPX test, v2 or cobas® MPX Test for the respective analyte when using the following products:

STN	Name of Biological Products
BL 125459/22*	cobas® TaqScreen MPX Test, v2.0 for use on the s 201 system
BL 125576/11	Multiplex HIV, HCV and HBV nucleic acid test for use on the cobas® 6800/8800 Systems

We will include information contained in the above-referenced supplements in your biologics license application files.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging Transfusion and Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov