



SUPPLEMENT APPROVAL
February 25, 2021

Roche Molecular Systems, Inc.
Attention: Ms. Caroline Sobek
4300 Hacienda Drive
Pleasanton, CA 94588-2722

Dear Ms. Sobek:

We have approved your request submitted September 16, 2020, received September 17, 2020, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to update hazard information on the product labeling for the following products (Product Code QHO) used on the cobas 6800 and cobas 8800 Systems.

STN Name of Biological Products

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BL 125575/56*	West Nile Virus Nucleic acid test for use in the cobas 6800/8800 Systems
BL 125576/61	HIV-1 Group O and M, HIV-2, HCV and/or HBV (HIV-1/HIV-2/HCV/HBV/Multiplex Discriminatory NAT/pool testing)
BL 125653/40	cobas Zika

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

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