



Our STN: BL125699/5

**SUPPLEMENT APPROVAL
May 6, 2020**

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

Dear Ms. Grewal:

We have approved your request submitted February 6, 2020, and received February 7, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for cobas® Babesia to add a pooling claim for testing whole blood samples in pools of up to 6 for use on the cobas® 6800/8800 System with cobas® Synergy Software.

We will include the information contained in the above-referenced supplement in your BLA file.

Sincerely,

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