



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

MEMORANDUM

Date:

From: Susan A. Zullo, Ph.D., CBER/OBRR/DETTD/PRB

Through: David Leiby, Ph.D., Chief, CBER/OBRR/DETTD/PRB

To: Vasantha Kumar, Ph.D., CBER/OBRR/RMPS

CC: Caren Chancey, Ph.D., CBER/OBRR/DETTD/LEP

Product: cobas Zika

STN: 125653

Sponsor: Roche Molecular Systems, Inc.

Subject: Final review memo for Testing Plan

Summary:

Roche Molecular Systems, Inc. submitted an original Electronic Biologics License Application (eBLA) for cobas Zika for priority review on April 7, 2017. The cobas Zika test is a qualitative *in vitro* nucleic acid screening test for the direct detection of Zika virus RNA in human plasma. The test is intended for use to screen donor samples for Zika virus RNA in plasma samples from individual human donors including donors of whole blood and blood components, and other living donors. The test is also intended for use to screen organ and tissues donors while donor samples are obtained while the donor's heart is still beating. The test is not intended for use as an aid in diagnosis of Zika virus infection. It is not intended for use on samples of other body fluids or for use on samples of cord blood. The cobas Zika test is for use on the cobas 6800 and cobas 8800 Systems.

CBER develops and approves a Lot Release Testing Plan to support and to document the decision to implement Lot Release and require sample submission as a condition of licensure. This plan also describes whether, and if so, how and under what conditions CBER intends to test the samples. Lot Release Testing Plans are intended to remain flexible over time in order for CBER to respond appropriately to protect public health in the face of new information. In developing Lot Release Testing Plans, CBER does not relinquish any rights or obligations under 21 CFR 610.2(a) or 21 CFR 814.82(a).

I reviewed and revised the final CBER Laboratory Quality Product Testing Plan for STN 125653 in collaboration with OCBQ/DBSQC.

Recommendation: I recommend that the Testing Plan for cobas Zika be finalized as a condition of licensure.