



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

## Final Review Memorandum – STN 125653\0

**Date:** September 25, 2017

**To:** Caren Chancey, PhD, OBRR/DETTD/LEP  
Vasanth Kumar, PhD, OBRR/RPMS

**Reviewer:** Michelle McClure, PhD, OTAT/DHT/HTRB

**Through:** Ping He, MD, OTAT/DHT/HTRB

**Sponsor/Product:** Roche Molecular Systems, Inc./cobas Zika test for use on the cobas 6800 and 8800 Systems

**Discipline(s) Reviewed:** Information submitted in support of claims specific to donors of HCT/Ps and organs

**Recommendation:** Recommend approval with one change to PI

**Precedent-Setting Product:** Yes – If approved, this would be the first licensed ZIKV NAT donor screening test.

**Indication:** Roche's current proposed intended use statement is as follows:

The cobas® Zika test for use on the cobas® 6800 and cobas® 8800 Systems is a qualitative in vitro nucleic acid screening test for the direct detection of Zika virus RNA in human plasma. This 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. This test is also intended for use to screen organ and tissue donors when donor samples are obtained while the donor's heart is still beating. Plasma from all donors should be screened as individual samples.

The test is not intended for use as an aid in diagnosis of Zika virus infection.

This test is not intended for use on samples of other body fluids.

This test is not intended for use on samples of cord blood.

**Documents** From STN 125653\0: cobas® Zika Draft Summary Basis for Approval; draft

**Reviewed:** Package Insert

***Discipline Summary:***

Roche's current proposed intended use includes a screening claim for donors of whole blood and blood components, other living donors, and organ and tissue donors whose blood specimens are collected while the heart is still beating. At this time, the proposed intended does not include cadaveric (non-heart-beating) organ and tissue donors. Since no cadaveric claim is being sought no related study data/summaries have been provided, this review is limited to review of sections of the package insert that relate to heart-beating organ and tissue donors.

Although the intended use will include living donors, a negative result in plasma does not necessarily mean that cells or tissues recovered are not infected.

***Discipline Comments:***

The sections of the package insert that relate to heart-beating tissue and organ donors have been reviewed. The labeling was found to be appropriate, however a note about ZIKV persistence in certain cells and tissues should be added.

This reviewer recommends approval pending the modification to the package insert described below.

***Letter-Ready Comment to Sponsor:***

The cobas Zika test is designed to detect Zika RNA in plasma samples, and Zika RNA may persist in certain organs and tissues, as well as other body fluids, longer than it is detectable in plasma. To avoid misunderstanding of the significance of a negative test result, please add a note stating such in your package insert.