



Memorandum

STN: **BL125653**

Date: **September 9, 2017**

Reviewer: **Swati Verma, Lot Release Protocol Reviewer**

Through: **David Asher, Chief LBTSEA/DETTD/OBRR/CBER**

To: **Chancey, SL**
Vasanth Kumar, RPM

Sponsor: **Roche Molecular Systems, Inc. (RMS)**

Product: **Cobas Zika NAT assay on the 6800/8800 system**

Subject: **Results of the coded Zika#29 testing performed by Roche Molecular Systems, Inc. Cobas® Zika test kit.**

Recommendation: **Approval**

Summary:

This memo provides the testing results of the coded Zika sets that were tested by RMS on the c6800/8800 systems for the licensure of cobas® Zika IVD (STN 125653/0). I recommend approval of the cobas® Zika test on the cobas 6800/8800 systems based on the decoded results of the three-blinded sets on three kit lots and comparison with the CBER established expected reactivity for the Zika panel#29 that was agreed by CBER and FDA during the review.

Background:

The cobas Zika test for use on the cobas 6800/8800 systems is a qualitative *in vitro* 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. The 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. This 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 cord blood or any other body fluids.

DETTD sample custodian shipped to Roche three sets of blinded randomized panels of the Zika lot release pane#29 to test using three kit lots of cobas® Zika IVD. The test results were decoded by DBSQC in parallel to DETTD and the results compared with the CBER established expected reactivities for the Zika panel#29. I have decoded and reviewed the test results and tabulated the

data of each of the blinded sets: A, B, and C.

Data reviewed:

Roche provided test results from three master lots: Y12974, YD2970 and YD2971 of the cobas® Zika test kit. Table 1, 2 and 3 provides the decoded results from Roche for each of the three sets. Ten samples were provided in each set with some members in duplicate.

Table1: Set#A decoded cobas® Zika test results performed on the cobas 6800/8800 systems

Set A	ID on the vial	Expected Reactivity established by CBER	Zika 480T YD2970 results
2901	A7	Reactive	Reactive
2902	A9	Reactive	Reactive
2903	A8	Reactive	Reactive
2903	A1	Reactive	Reactive
2904	A6	Reactive	Reactive
2904	A4	Reactive	Reactive
2905	A10	Reactive or Non-Reactive	Non-Reactive
2905	A2	Reactive or Non-Reactive	Reactive
2906	A3	Non-Reactive	Non-Reactive
2907	A5	Reactive or Non-Reactive	Non-Reactive

Table2: Set#B decoded cobas® Zika test results performed on the cobas 6800/8800 systems

Set B	ID on the vial	Expected Reactivity established by CBER	Zika 480T Y12974 results
2901	B3	Reactive	Reactive
2902	B7	Reactive	Reactive
2903	B9	Reactive	Reactive
2903	B5	Reactive	Reactive
2904	B8	Reactive	Reactive
2904	B2	Reactive	Reactive
2905	B10	Reactive or Non-Reactive	Reactive
2906	B6	Non-Reactive	Non-Reactive
2907	B1	Reactive or Non-Reactive	Non-Reactive
2907	B4	Reactive or Non-Reactive	Non-Reactive

Table3: Set#C decoded cobas® Zika test results performed on the cobas 6800/8800 systems

Set C	ID on the vial	Expected Reactivity established by CBER	Zika 480T YD2971 results
2901	C7	Reactive	Reactive
2902	C6	Reactive	Reactive
2903	C3	Reactive	Reactive
2903	C5	Reactive	Reactive
2904	C2	Reactive	Reactive
2904	C8	Reactive	Reactive
2905	C4	Reactive or Non-Reactive	Reactive
2905	C1	Reactive or Non-Reactive	Reactive
2906	C10	Non-Reactive	Non-Reactive
2907	C9	Reactive or Non-Reactive	Reactive

Conclusions:

The results submitted by RMS demonstrated that the Cobas® Zika nucleic acid test was able to successfully and accurately detect the presence or absence of the Zika RNA in the samples. The test results of the three master lots of the coded panels were in compliance of the expected reactivities established by CBER.

After the thorough review of the lot release protocol of the master lots: Y12974, YD2970 and YD2971 submitted by Roche for the licensure of Cobas® Zika nucleic acid test for use on the c6800/8800 systems, I recommend the approval of the test.