



Filing Meeting Summary:

- **Meeting Date:** **May 22, 2017**
- **Meeting Time:** **12:00-1:00pm (EDT)**
- **Meeting attendees:** Chancey, Caren; Ketha, Krishna; Volkova, Evgeniya ; Rios, Maria; Lathrop, Julia; Syed, Sajjad H; Jones, Cecily; Jones, Dana; Chun, Haecin; McClure, Michelle; Crise, Bruce; Verma, Swati; Francis, Kori; Anderson, Marie; Leiby, David; Asher, David; Hewlett, Indira; Eder, Anne; Trout, Deborah; Kelly, Sonday; Renshaw, Carolyn; Eltermann, John; Kumar, Vasantha

Submission Details:

- **Application Number:** **STN 125653/0**
- **Applicant:** **Roche Molecular Systems, Inc.**
- **License #:** **1636**
- **Application Type:** **Original BLA**
- **Device Name:** **cobas® Zika**
- **Submission Link:**

(b) (4)

- **Review Schedule:** **Priority Review- 6 Month Review**
- **Associated Reference submission:** **IND# 16926 ('Search' 16926 in the EDR)**
- **Summary:** cobas® Zika is a qualitative test that is run on the cobas® 6800 System and cobas® 8800 System. cobas® Zika enables the simultaneous detection of Zika RNA and the internal control in a single test of an infected, individual donation.
- **Intended Use:**
The cobas® Zika test for use with the cobas® 6800/8800 System, is a qualitative in vitro nucleic acid screening test for the direct detection of Zika virus RNA in plasma specimens from individual human donors, including donors of whole blood and blood components, and other living donors. It is also intended for use in testing plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating. The test is not intended for use as an aid in diagnosis. The test is not intended for screening other body fluids. This test is not intended for use on samples of cord blood.

Review Team:

RPM- Vasantha Kumar

Lead Reviewer- Caren Chancey

Clinical- Julia Lathrop

Non-clinical- Krishna Ketha

CMC- Evgeniya Volkova; Maria Rios (CMC)

Statistics- Tie-Hua Ng

Software- Sajjad Syed

DMPQ- Cecily Jones (Debbie Trout- Consult)

BIMO- Haecin Chun

APLB- Dana Jones

OTAT/DHT- Michelle McClure; Bruce Crise (include Ping He)

DBSQC- Kori Francis; Marie Anderson Bioburden- Hyesuk Kong

Lot Release (DETTD)- Swati Verma

Product Specific Issues- Sanjai Kumar; Pradip Akolkar; David Leiby; Indira Hewlett; David Asher; Ann Eder

DETTD Reg Policy/Managed Review- Sayah Nedjar

Senior Management- Peyton Hobson; Hira Nakhasi

Filing Meeting Discussion:

1. Confirm review schedule of this application. [Standard Review, **Priority Review**, or Expedited Review]
Yes, this would be a Priority review
2. Review the submission for any Refuse To File (RTA) issues
There are no RTA Issues; the submission will be filed
3. Indicate any comments on the status of the labeling of the product
Labelling to be finalized
4. Indicate the decision regarding the need for an Advisory Committee.
Review team and the management feels no need for advisory committee
5. Is a comprehensive and readily located list of all clinical sites included or referenced in the application?
Yes
6. Is a comprehensive and readily located list of all manufacturing facilities included or referenced in the application?
Yes
7. Any lots for testing? Comments requested from the Lot release team
No issues identified now
8. Indicate any updates since the First Committee Meeting on pre-license inspection, pre-approval inspection, or BIMO sites requiring inspections (Is the establishment(s) ready for inspection?)
No deficiencies identified
9. Any other matter of significance?
None
10. An email from each reviewer is required with the recommendation for filing by **June 1, 2017**
(Subject: 125653/0. Cobas Zika. Roche. Filing Recommendation)
Reviewers have provided their individual filing recommendation via email/memo and has been uploaded in the EDR

-END-

Vasantha Kumar

Vasantha Kumar, Ph.D.

Regulatory Project Manager

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