

## Meeting Minutes for the VQA Advisory Board Conference Call

April 16, 2021

Taken by Miranda Carper and Terese Camp, Duke VQA

### Attendees:

#### VQAAB Voting Members

- |  |   |  |
|--|---|--|
| <input checked="" type="checkbox"/> Bill Meyer (Chair)           | <input checked="" type="checkbox"/> Robert Coombs (ACTG/HVTN) | <input checked="" type="checkbox"/> Nicole Tobin (IMPAACT) |
| <input checked="" type="checkbox"/> Joan Dragavon (ACTG/HVTN)    | <input checked="" type="checkbox"/> Urvi Parikh (MTN)         | <input checked="" type="checkbox"/> Jessica Fogel (HPTN)   |
| <input checked="" type="checkbox"/> Belinda Yen-Lieberman (ACTG) | <input type="checkbox"/> Grace Aldrovandi                     | <input checked="" type="checkbox"/> Marco Schito           |

#### VQAAB Non-Voting Members

- |  |   |  |
|--|---|--|
| <input checked="" type="checkbox"/> Ron Bosch (SDAC) | <input checked="" type="checkbox"/> Diane Costello (IMPAACT/ACTG) | <input checked="" type="checkbox"/> Fatima Jones (NICHD) |
| <input type="checkbox"/> Saira Huq (NICHD)           |   |  |

#### HANC

- Tyler Brown

#### NIAID/DAIDS

- |  |  |
|--|--|
| <input checked="" type="checkbox"/> Joe Fitzgibbon | <input checked="" type="checkbox"/> Keith Crawford |
|--|--|

#### Virology Quality Assurance / Duke Human Vaccine Institute

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Thomas Denny (PI)            | <input checked="" type="checkbox"/> Raul Louzao   | <input checked="" type="checkbox"/> Terese Camp    |
| <input checked="" type="checkbox"/> Bhavna Hora       | <input checked="" type="checkbox"/> Sal Scianna   | <input checked="" type="checkbox"/> Heidi Register |
| <input type="checkbox"/> Wes Rountree                 | <input checked="" type="checkbox"/> Katelyn Xiang | <input type="checkbox"/> Marcella Sarzotti-Kelsoe  |
| <input checked="" type="checkbox"/> Kristen Skinner   | <input type="checkbox"/> Chris Todd               | <input checked="" type="checkbox"/> Miranda Carper |
| <input checked="" type="checkbox"/> Zach Korzen-Varin | <input checked="" type="checkbox"/> Yunfei Wang   |  |

#### Virology Quality Assurance Sub-Contractor

- Mike Busch (Vitalant Research Institute)

### Action Items

- VQA add number of labs participating for each PT to Mean Log<sub>10</sub> Recovery by Kit Type Figure
- VQA investigate if amplification of GEN2020\_11 sample 4 is due to a kit lot issue. Send results of investigation to VQAAB and request their vote off-line

### Meeting Minutes

- Opening Remarks
  - Bill Meyer and Tom Denny
- Roll Call
  - Miranda Carper
  - 8 voting members were present
- Review of Data
  - RNA2021\_02
    - 73 datasets from 53 laboratories were included in the analysis

- 3 datasets received a score of PC
- 1 dataset received a score of P
- Potential Issue Alerts were not released for this PT
  - Change in panel samples impacted labs; particularly those running RTM assays. Continue to monitor performance in upcoming PTs
    - RTM labs had higher standard deviation
- Change in Status
  - Two laboratories are reapproved for testing
  - One laboratory had a decline in status from approved to provisionally approved for testing
- VQA reviewed graphs showing the Mean Log<sub>10</sub> Recovery by Kit Type for all VQA PT data and for VQA200 copy control data.
  - Action: Add number of labs for each kit type to graphs
- VQAAB voted and approved the scores calculated by the VQA
- GEN2021\_11
  - Call for vote to remove sample four from analysis
    - Several laboratories had issues amplifying sample 4 (HIV-1 Subtype C) for PR/RT; Majority of the labs that had issue were those using the ViroSeq assay (see **Table 1** below)
    - Summary of Review of data and quality control testing
      - Samples were tested using in-house NGS, in-house Sanger and ViroSeq assay
      - VQA sequencing core did not have issues amplifying any of the samples
      - Phylogenetic tree analysis was performed on the data, no other issues were identified with sample 4
    - Advisory Board asked if the issues amplifying sample 4 is a kit lot issue
      - Advisory Board Advice: If the problem is not due to the kit, then don't change the scores. If it is a kit lot issue the sample should be removed
      - Action VQA: investigate if this is a kit lot issue and provide the information to the VQAAB to vote via email
    - Post Meeting Note: All five laboratories that had issues amplifying sample 4 were using the same ViroSeq kit lot (50422). The VQAAB voted to remove sample four from analysis due to technical reasons (kit lot issue for ViroSeq). Sample 4 was removed for PR/RT and new reports were created and provided to the laboratories. Sample 4 remained in in INT analysis.
- Closing statement
  - VQAAB Annual Review
  - On-site September 20, 2021

**Table 1: Summary of laboratories that were unable to amplify sample 4**

<b>Number of PR/RT datasets</b>	47
<b>Number of labs unable to amplify sample #4 PR/RT</b>	7
<b>% of labs had problems with # 4 PR/RT</b>	14.89%
<b>Number of VS labs unable to amplify sample #4 PR/RT</b>	5
<b>Total number of VS labs PR/RT</b>	9
<b>% of VS labs had a problem with # 4 PR/RT</b>	55.56%
<b>% of labs had problems with # 4 PR/RT</b>	14.89%
<b>Number of labs that would have a score change if remove sample 4 from analysis</b>	2 PR/RT, 1 INT