

Meeting Minutes for the VQA Advisory Board Conference Call

December 18, 2020

Taken by Miranda Carper, Duke VQA

Attendees:

VQAAB Voting Members

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|--|---|--|
| <input checked="" type="checkbox"/> Bill Meyer (Chair) | <input type="checkbox"/> Robert Coombs (ACTG/HVTN) | <input 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

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|--|---|---|
| <input checked="" type="checkbox"/> Ron Bosch (SDAC) | <input checked="" type="checkbox"/> Diane Costello (IMPAACT/ACTG) | <input type="checkbox"/> Meghal Patel (NICHD) |
| <input checked="" type="checkbox"/> Lori Merrill (NICHD) | <input checked="" type="checkbox"/> Linda Robbins (ACTG/HVTN) | |

HANC

- | | |
|--------------------------------------|--|
| <input type="checkbox"/> Tyler Brown | <input checked="" type="checkbox"/> Milan Vu |
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NIAID/DAIDS

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

Virology Quality Assurance / Duke Human Vaccine Institute

- | | | |
|---|---|--|
| <input checked="" type="checkbox"/> Thomas Denny (PI) | <input checked="" type="checkbox"/> Raul Louzao | <input type="checkbox"/> Feng Gao |
| <input checked="" type="checkbox"/> Andrea Pappas | <input checked="" type="checkbox"/> Sal Scianna | <input checked="" type="checkbox"/> Heidi Register |
| <input checked="" type="checkbox"/> Wes Rountree | <input checked="" type="checkbox"/> Katelyn Xiang | <input checked="" type="checkbox"/> Marcella Sarzotti-Kelsoe |
| <input checked="" type="checkbox"/> Kristen Skinner | <input type="checkbox"/> Chris Todd | <input checked="" type="checkbox"/> Miranda Carper |

Virology Quality Assurance Sub-Contractor

- | |
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| <input checked="" type="checkbox"/> Mike Busch (Vitalant Research Institute) |
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Action Items

- VQA: contact lab that received a score of P about RNA2020_10 data and ask for instrument to instrument validation for back-up instrument. Notify HPTN of issues with back-up instrument.
- VQA: create a Doodle poll to schedule the first VQAAB meeting in 2021.

Meeting Minutes

Opening Remarks

Bill Meyer & Tom Denny

Roll Call

Miranda Carper

Review of Data: RNA2020_10, DNA2020_09, GEN2020_5

Salvatore Scianna & Miranda Carper

Call for vote to approve VQA Participation Survey:

Bill Meyer

<https://form.jotform.com/203173968497066>

Call for vote to approve VQAAB Annual Review Bill Meyer

(VAR) Executive Summary

Proposed VQAAB Schedule for 2021

Miranda Carper

Closing statements or Questions

Bill Meyer

- Opening Remarks were led by Bill Meyer and Tom Denny
- Roll Call
 - Was taken by Miranda Carper
 - There were 6 voting members present
- Review of Data
 - Sal Scianna and Miranda Carper discussed the following data:
 - RNA2020_10
 - 89 dataset submitted by 64 laboratories; 2.2% of labs had a score of PC or P
 - 1 laboratory had a score of P
 - Lab switched to back-up instrument. VQAAB expressed concern that the back-up instrument had poor performance. VQAAB suggested that the VQA contact the lab to share instrument to instrument validation.
 - 1 laboratory had a score of PC
 - 5 laboratories received a Potential Issue Alert for STD Deviation or Accuracy
 - Two labs who perform testing using the Roche Cobas received a PIA. It was noted in the meeting that the RCo has a higher recovery than some of the other assays and on occasion someone will tip above the 2 standard error.
 - Additional Note
 - Dataset 76 - Laboratory data for RNA2020_10 was analyzed 2x. Laboratory indicated they wanted to report testing of RNA2020_08 (PC) in IR report. The note in the IR was seen after the laboratory submitted data for RNA2020_10 and received a score of PC. VQA reanalyzed RNA2020_10 with replacement data for RNA2020_08.
 - Change in status
 - 1 laboratory had a decline from Approved to Provisionally Approved
 - 2 laboratories were newly approved for testing
 - 4 labs are reapproved for testing
 - DNA2020_09
 - Secondary analysis
 - 2 datasets from 2 laboratories
 - 1 Dried Blood Spot (DBS) panel and 1 Whole Blood (BLD) panel
 - Both labs received a score of C
 - GEN2020_5
 - Primary analysis
 - PR/RT: 34 data sets from 29 laboratories
 - 3 Laboratories received a score of PC
 - 1 Laboratory had stage 1, 2, and 3 errors for samples 1 and 3. VQAAB is concerned this laboratory received a score of PC for two PTs in a row. Lab received a score of C for INT testing

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- Question was raised regarding the if a lab starts protocol testing using the Abbott platform and later switches to Roche or Hologic Panther platform, are their biases for the instruments. Could the VQA help the study leaders understand the biases.
- Bill Meyers suggested if there are questions, to contact him, M. Carper, or T. Denny. A call can be scheduled with the study leaders and the VQA can use their historical knowledge to answer any questions regarding limit of detection and the different assays used in protocol testing.

