

Meeting Minutes for the VQA Advisory Board Conference Call

December 18, 2020 Taken by Miranda Carper, Duke VQA

Attendees:

VQAAB Voting Members

⊠Bill Meyer (Chair) ⊠Joan Dragavon (ACTG/HVTN) ⊠Belinda Yen-Lieberman (ACTG)	□Robert Coombs (ACTG/HVTN) ⊠Urvi Parikh (MTN) □Grace Aldrovandi	□Nicole Tobin (IMPAACT) ⊠Jessica Fogel (HPTN) ⊠Marco Schito	
VQAAB Non-Voting Members			
⊠Ron Bosch (SDAC) ⊠Lori Merrill (NICHD)	⊠Diane Costello (IMPAACT/ACTG) ⊠Linda Robbins (ACTG/HVTN)	□Meghal Patel(NICHD)	
HANC			
□Tyler Brown	🖾 Milan Vu		
NIAID/DAIDS			
□Joe Fitzgibbon	⊠Keith Crawford		
Virology Quality Assurance / Duke Human Vaccine Institute			
⊠Thomas Denny (PI) ⊠Andrea Pappas ⊠Wes Rountree ⊠Kristen Skinner	⊠Raul Louzao ⊠Sal Scianna ⊠Katelyn Xiang □Chris Todd	□Feng Gao ⊠Heidi Register ⊠Marcella Sarzotti-Kelsoe ⊠Miranda Carper	

Virology Quality Assurance Sub-Contractor

Mike Busch (Vitalant Research Institute)

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 RemarksBill Meyer & Tom DennyRoll CallMiranda CarperReview of Data: RNA2020_10, DNA2020_09,
GEN2020_5Salvatore Scianna & Miranda CarperCall for vote to approve VQA Participation
Survey:
https://form.jotform.com/203173968497066Bill Meyer



Call for vote to approve VQAAB Annual Review **Bill Meyer** (VAR) Executive Summary Proposed VQAAB Schedule for 2021 **Closing statements or Questions**

Miranda Carper **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:
 - o 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 then 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 0
 - 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 0
 - . 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. 0 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

VQA 🖤 Duke Human Vaccine Institute

- Post Meeting Note: Lab submitted IR form after the VQAAB Meeting. Error was due to the samples that were being tested were switched.
- Two laboratories received a score of PC because they were unable to amply one sample. Note the labs were unable to amplify different samples. Both labs performed extensive analysis to identify the issues. One of the labs was performing testing using the ViroSeq assay and indicated in their IR that they will switch to the Vela Sentosa SQ HIV-1 Genotyping assay.
- INT: 20 data sets from 19 laboratories
- 1 prequalification panel was tested using the Vela Sentosa SQ HIV-1 Genotyping assay
 - Laboratory received a score of PC for Integrase. Due to the 5% threshold the instrument was set at. The lab was picking up mixtures that was not found in the consensus sequence. The lab was contacted and will resubmit data for reanalysis.
- Call for vote to approve VQA Participation Survey: <u>https://form.jotform.com/203173968497066</u>
 - VQAAB approved of the survey and choice of questions
- Call for vote to approve VQAAB Annual Review (VAR) Executive Summary
 - VQAAB approved the VAR Executive Summary
- Proposed VQAAB Schedule for 2021
 - Duke VQA proposed a meeting schedule for 2021. Dates were strategically chosen to decrease the amount of time between data analysis and the VQAAB meetings.
 - Duke VQA will send a doodle poll to schedule the first meeting.

Proposed VQAAB Meeting Schedule for 2021			
PT to Discuss	PT Date	Proposed Meeting Date	
VQAAB 2021.1*			
RNA2020_12	12-01-20 to 12-18-20	Week of January 25, 2021 or	
		February 1, 2021	
VQAAB 2021.2			
GEN2020_11	11-30-20 to 01-08-21	Week of April 5, 2021	
RNA2021_02	02-08-21 to 02-26-21	Week of April 5, 2021	
VQAAB 2021.3			
DNA2021_03	03-08-21 to 03-26-21	Week of lune 29, 2021	
RNA2021_05	05-03-21 to 05-21-21	Week of June 28, 2021	
VQAAB 2021.4 (VQAAB Annual Review Meeting YR2)			
GEN2021_05	05-17-21 to 06-25-21	Week of September 20, 2021 if on	
RNA2021_08	08-02-21 to 08-20-21	site. Week of October 11, 2021 if	
		virtual	
VQAAB 2021.5			
DNA2021_09	09-13-21 to 10-01-21	December 17, 2021	
RNA2021_11	11-01-21 to 11-19-21		

* Short meeting to discuss RNA2020_12 data and the removal of labs from VQA

Closing statements or Questions



- 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.

