

Meeting Minutes for the VQA Advisory Board Conference Call

June 19, 2020

Taken by Miranda Carper, 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 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) | | |

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 checked="" type="checkbox"/> Thomas Denny (PI) | <input checked="" type="checkbox"/> Raul Louzao | <input checked="" 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 type="checkbox"/> Marcella Sarzotti-Kelsoe |
| <input checked="" type="checkbox"/> Kristen Skinner | <input checked="" type="checkbox"/> Todd DeMarco | <input checked="" type="checkbox"/> Miranda Carper |

Virology Quality Assurance Sub-Contractor

- ☒ Mike Busch (Vitalant Research Institute)

Action Items

- Survey VQAAB for best date to have the VQA face-to-face meeting.

Meeting Minutes

- Opening Remarks and Roll Call
 - Thomas Denny welcomed the advisory board members on the call
 - Miranda Carper took roll call
 - There were 8 voting members on the call
 - Meeting minutes from call on April 17, 2020 were accepted
- Presentation: "Overview of Duke VQA Environment and Activity in Light of COVID-19"
 - Presenter: Miranda Carper
 - VQA presented a brief overview of the following topics:
 - Duke environment and staffing policies
 - Duke is reinitiating "non-essential" laboratory operations
 - Social distancing is being maintained

- Reduced number of Staff in Laboratory
 - Staff will work in shifts
 - Staff will work remotely when possible
- Resuming VQA operations
 - 2 on-going/upcoming PTs
 - Quantitative HIV-1 RNA Testing
 - Data collection started June 8th
 - Data due June 26th
 - HIV-1 Drug Resistance Sequencing
 - VQA will confirm all international panels are scheduled on flights and approved for shipment
 - Sites will be given two week notice prior to shipment
 - Courier: BioCair and World Courier
 - Policies of Laboratory is unable to participate
 - Laboratory must email VQA if there are problems completing the PT
 - VQA will work with the lab for the best solution
 - Options
 - Put the lab on hold
 - Extend due date for laboratory
 - Exemption for current PT
 - Shipping
 - VQA is working with couriers to find flights to ship QCMs
 - Starting to see large influx of orders
 - Restricting how many controls a lab can order at a time until able to supplement inventory with productions
 - Limited in amount of staff available to prep shipments
 - Production
 - Production while maintaining social distancing
 - Unable to package larger productions due to space and social distancing requirements
 - Panel and control productions must be spread out over multiple shifts or days
 - Smaller productions allow for quicker turnaround with fewer staff but must be done more frequently to supplement inventory
 - Plan for possible future shutdowns
 - Solution for labs to have controls for clinical testing
 - Provide lab with protocol for creating their own controls and QC recommendations
 - Pool samples to create controls
 - Send high titer virus stock to labs in South America, Africa, Vietnam, and Thailand
 - Lab can share high titer stock with other laboratories to make controls

- VQAAB suggestion: interim CAP can be used (if available to international site)
- VQA/IVQAC COVID-19 work
 - Sequencing of SARS-CoV-2
 - Efforts led by Feng Gao
 - Sequenced nasopharyngeal swab (NPS) samples for the SARS-CoV-2 spike gene from patients that tested positive for SARS-CoV-2
 - 3/3 samples negative for SARS-CoV-2 were negative after performing the amplification
 - Sequenced S gene for 10 samples from NC
 - All 10 samples had D614G mutation which is associated with increased infectivity
 - Two other sequences have 1 or 2 additional mutations but they are not in the receptor binding site and we think is a product of the amplification
 - Development of a quantitative SARS-CoV-2 LDT assay
 - Development spearheaded by Todd DeMarco
 - Description of work flow
 - NPS samples are collected by Duke Clinicians. Samples are processed and qPCR performed in accordance with our workflow for our validated NHPCVL (Non-human primate core virology laboratory) SIV viral load assay
 - 4 primer probe sets were tested
 - Moving forward the WHO-E primer set was used
 - Currently Todd DeMarco is completing the validation of the instrument. Todd created a validation panel by spiking in inactivated SARS-CoV-2 genomic RNA into DMEM
 - In-house validation panel created to cover expected clinical range of SARS-CoV-2 viral loads
 - Bob Coombs is interested in getting the validation panels
 - The IVQAC is currently working to complete the validation, assay is able to pick up as low as 62 copies / mL
 - SARS-CoV-2 antibody assay
 - IVQAC is currently testing clinical samples for the presence of SARS-CoV-2 antibodies using different kits
 - EUROIMMUNE IgG: Measures antibody response to S1 domain of the spike protein (qualitative)
 - Akston Biosciences (antiCov-ID): Measures antibody response to Spike protein receptor binding domain (RBD, quantitative)
 - GenScript SARS-CoV-2 Surrogate Virus Neutralization Test (sVNT) Kit: Antibodies and RBD are mixed and then added to a

plate coated with the ACE2 receptor (neutralization assay surrogate)

- Tested panel of SARS-CoV-2 Antibody testing and Serology Comparison of Seasonal Influenza Cross Reactivity
 - Goal: determine sensitivity of assays
 - Seasonal Respiratory panel (~35 samples) did not cross react using the Akston assay
 - Few samples cross re-acted using the EUROIMMUN and GenScript assays
 - Working with company to see if cross-reactivity is due to cutoff limits
 - IVQAC is involved in performing Seroprevalence Monitoring with the Duke Emergency Department
 - In early April approximately 3.52% of patients testing positive for SARS-CoV-2 IgG antibodies
 - Repeat study in July
 - IVQAC is measuring IgG response from samples collected at different time points
- Closing Statements
 - Duke VQA will send-out a survey for the virtual “face to face” VQAAB meeting
 - Take place either October 8/9 or October 15/16