

26 Mar 2020

Dear Participants of the IQA, VQA, EQAPOL, and NHPCVL Programs,

For the safety of our faculty and staff, Duke University has implemented new policies that discontinue any non-essential work and encourages those who are able, to work remotely. We at the Duke Human Vaccine Institute (DHVI) are still dedicated to meeting our mission and providing support for the new challenges created by COVID-19. This means, we will continue to provide support toward vaccine development, COVID19 diagnostic and therapeutic studies, and analysis of samples from non-human primate studies. We unfortunately will be canceling or postponing proficiency testing (PT) or external quality assurance (EQA) send-outs in the next couple of months. Please note that we will continue to analyze data and generate reports for results that have been collected or kits that have been sent out (PT/EQA, investigation reports, and validation reports). Please contact us if you have any questions or concerns about results that are pending. We have worked with the contracting officer representatives (CORs) for the IQA, VQA, EQAPOL, and NHPCVL programs and compiled a summary below describing the plan for each program.

Immunology Quality Assessment (IQA) Program

- **Cryopreservation PT**
 - February/March PT
 - Due date: March 13, 2020
 - IQA is completing a round of testing.
 - IQA will continue to generate reports
 - Lab reports
 - Investigation reports
 - May/June PT
 - Due date : June 12, 2020
 - **PT is canceled**
- **Domestic CD4 PT**
 - Closed March 13, 2020
 - IQA will continue to generate reports
 - Lab reports
 - Investigation reports
 - Next PT is scheduled to continue in September
 - IQA and NIAID will continue to monitor the situation and inform labs of any future changes
- **International CD4 / UK-NEQAS PT**
 - Frequency every two months
 - PT was just shipped out.
 - **Next PT scheduled to Ship in May is cancelled**

- IQA and NIAID will continue to monitor the situation and inform labs of any future changes
- **Leukapheresis Real Time QA**
 - **Cancelled at this point in time**

Virology Quality Assurance (VQA) Program

- HIV-1 Qualitative Nucleic Acid PT
 - DNA2020_03
 - Shipped March 3rd (BLD) and 5th (DBS)
 - Due Date March 27, 2020
 - Due to delays caused by COVID-19, some labs have or will receive the whole blood (BLD) shipment past the 10 day window
 - If labs received blood beyond March 13, 2020, they may still continue to test the blood and submit results to the VQA. Labs will not get penalized if they receive a lower score due to integrity of the blood sample.
 - VQA will continue to generate the following:
 - Lab performance reports
 - Investigation reports
- Un-blinding of the Qualitative Nucleic Acid Controls
 - It was decided to postpone the un-blinding of the HIV-1 Qualitative Nucleic Acid controls. Sites may continue to verify blinded control sites using the LDMS system, by emailing Frontier Science, or by using the blinding key.
- Quantitative HIV-1 RNA PT
 - RNA2020_04
 - On March 18, 2020 Duke VQA sent-out a survey to gauge the ability of the labs to perform analysis of the PT samples
 - **The RNA2020_04 PT is cancelled**
- HIV-1 Drug Resistance PT
 - GEN2020_05
 - **It was decided to postpone the shipment of the next panel from May 1st to June 5th 2020**
 - VQA and NIAID will continue to monitor the situation and inform labs of any future changes
- Validations and controls
 - Shipment of VQA controls, including those used in validations, are being impacted by the COVID-19 crisis. Duke VQA will let the laboratories know if we are unable to complete your shipment at this time.
 - VQA will continue to analyze validation data and generate reports

External Quality Assurance Program Oversight Laboratory (EQAPOL)

- Luminex EQA send-out
 - Ship Date April 27, 2020
 - **Cancelled**
- Flow EQA send-out
 - Ship Date June 1, 2020
 - **Cancelled**

- EQAPOL and NIAID will continue to monitor the situation and inform labs of any other future changes

Non-Human Primate Core Virology Laboratory (NHPCVL)

- Duke will have one person on site every day that can receive and perform the analysis of non-human primate samples, however only samples from non-infected animals should be sent for testing.
 - It is critical to know if animals are infected and if the animals should still be challenged
 - Samples from infected animals should be stored in -80C for analysis at a later time.

Please reach out to us if you have any questions; we will continue to have staff available to monitor email and to answer any questions.

We hope everyone is doing ok and remains safe despite current circumstances.

Best Regards,

A handwritten signature in black ink that reads "Thomas N. Denny". The signature is written in a cursive, slightly slanted style.

Thomas Denny

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