MEMO

DATE: May 1, 2020

FROM: Laboratory Centers of the HIV Vaccine Trials Network (HVTN), HIV Prevention Trials Network (HPTN), the Microbicide Trials Network (MTN), the AIDS Clinical Trials Group (ACTG), the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Group

TO: DAIDS HIV/AIDS Clinical Trials Networks Laboratory Sites

SUBJECT: Guidelines for Network Lab Operations Recovery

In response to operational disruptions imposed by the COVID-19 pandemic, the Laboratory Centers of the DAIDS HIV/AIDS Clinical Trials Networks are providing a high-level guidance document for labs that have experienced workload/workforce reductions and temporary closures. To assist in a smooth transition back into work areas, we offer the following recommendations:

Communication

- Provide notifications to your clinics, reference labs, and networks regarding your lab's status, level of operations, and dates of any changes (include future dates if proposed changes/timelines are provided).
- Verify availability of any third party responsible for completing any aspect of operations (e.g., receipt of incoming shipments, preparation of outgoing shipments).
- Notify network(s) of any issues that might negatively impact lab's ability to perform study-specific functions optimally.
- If lab closure occurred during usual scheduled period for audit, contact network(s) to relay potential rescheduling info or need for further postponement to DAIDS.

Personnel Safety

- Follow local/regional practices, policies, and laws related to workplace safety resulting from pandemic responses. Local/regional guidelines will supersede any guidance provided by the network(s). Please inform the network(s) if conflicts noted.
- Follow region specific guidance re. workplace risk management (e.g., personal distancing, disinfection of work area/equipment). Adjust safety procedures accordingly; provide related training to staff.

- Verify adequate PPE supply for continued laboratory operations.
- Be mindful of aerosols when managing specimens.
- Consider potential impacts on waste management practices at your facility.

Documentation

- Complete formal documentation of lab downtime/disruption of service; address gaps in maintenance records, temperature logs, QC runs, etc.
- Address any excursions or deviations that occurred during downtime that have not already been resolved; complete related documentation to include corrective/preventive actions.

Equipment

- Complete equipment start-up procedures as defined by manufacturer; perform operational checks, including visual verification of properly functioning equipment (don't forget printers, scanners).
- Verify proper operation of computers and software. Perform backups and exports of data.
- Determine if calibrations are due/overdue. Is scheduled maintenance due/overdue? Are scheduled verifications due/overdue (e.g., alarm systems, pipettors, thermometers, centrifuge speeds/timers, etc.)?
    - Determine if your facility/institution will allow visitors/third party vendors/contractors access.
    - Determine if appropriate PPE is available for any visitors to your laboratory.
    - Contact third party vendors to inquire about availability of personnel for performing scheduled maintenance.

Assays, Reagents, and Supplies

- Check and document current stock levels and expiration dates of test kits/reagents/media/other consumables, supply chain issues, and possible storage temperature excursions. Perform and document visual verification of stored items for discoloration, bacterial growth, sedimentation or other indication of need for replacement.
- Perform assay/method quality control runs to determine acceptability. Perform (at a minimum) a mini-precision run for quantitative assays/methods (five short-term runs, for example); compare with historical performance of assay/method. If any issues discovered, re-validation may be necessary.

- Review EQA status, determine access to EQA shipments and ability to import (if applicable). Plan for EQA testing either with old EQA panels, other EQA sources, or perform cross-lab (interlab) comparisons.
- Perform method-to-method comparisons if due (e.g., primary vs. backup; manual vs. automated counting, tech-to-tech).
- Re-verify water supply, if applicable.

Managerial / Secondary Review and Follow-up

- Complete managerial/secondary review of all lab re-implementation documents as captured in above steps. Complete pending managerial/secondary reviews from before shutdown.

Training / Competency Assessment

- Determine if any training requirements have been exceeded (e.g., required timelines for refresher courses, competency assessments, periodic training such as shipping certification).
- Seek re-certification/re-qualification if lapses indicate need.

Laboratory Document Control

- Verify SOPs in use are current version. Are any due/overdue for review/revision? Verify correct versions of SOP attachments are in use (e.g., maintenance logs).
- Verify network documents are current versions (e.g., network SOPs, study-specific site lab instructions, laboratory requisitions, worksheets, etc.).
- Verify all required staff have read/understood any new or updated SOPs.
- Verify continued integrity of document management (e.g., archive/offsite records storage).

Specimen Management

- If specimens are ready for shipment, verify (*before* making LDMS shipping entries) that there are no shipping disruptions and verify destination lab/repository can receive specimens.

APPENDIX

Network-specific Guidelines

ACTG

- For labs with ACTG PBMCs in liquid nitrogen: Before completing shipment preparation, notify ACTG Lab Center at actg.labcenter@fstrf.org with summary of plan for shipment prior to shipping samples to BRI. This plan must be approved before proceeding until otherwise notified.
- For labs with ACTG PBMCs stored at -80 degrees for more than three weeks: provide the ACTG Lab Center a list of all PBMC PTID visits per protocol that are impacted before shipping specimens to repository.

HPTN

- For labs with pending shipment to the HPTN Lab center, the HPTN LC will communicate when shipments can resume.
- Continue to notify the HPTN Lab Center with any inventory related issues.

HVTN

- For labs with HVTN PBMCs in liquid nitrogen: Before completing shipment preparation, notify HVTN Lab Center with summary of plan for shipment. This plan must be approved before proceeding.
- For labs with HVTN PBMCs stored at -80 degrees for more than three weeks: provide HVTN Lab Center a list of all PBMC PTID visits impacted before shipping specimens to repository.
- For labs with pending HVTN HIV Diagnostics (not yet sent to the network-approved HIV Dx testing labs): ship specimens for testing as usual; if fewer than three vials sent (i.e., vial used for local testing) include impacted PTID visits in notification to HDTL.
- Review/resolve any pending IQC and EQC reports (HVTN processing labs in ATLAS).
- Resolve pending SDQCs (HVTN and HPTN processing labs).

HVTN and HPTN (joint studies)

- For labs with HVTN PBMCs in liquid nitrogen: Before completing shipment preparation, notify HVTN Lab Center with summary of plan for shipment. This plan must be approved before proceeding.

- For labs with HVTN PBMCs stored at -80 degrees for more than three weeks: provide HVTN Lab Center a list of all PBMC PTID visits impacted before shipping specimens to repository.
- For labs with pending HVTN HIV Diagnostics (not yet sent to the network-approved HIV Dx testing labs): ship specimens for testing as usual; if fewer than three vials sent (i.e., vial used for local testing) include impacted PTID visits in notification to HDTL.
- Review/resolve any pending IQC and EQC reports (HVTN processing labs in ATLAS).
- Resolve pending SDQCs (HVTN and HPTN processing labs).

IMPAACT

- For labs with IMPAACT PBMCs in liquid nitrogen: Before completing shipment preparation, notify IMPAACT Lab Center at impaact.qaqc@fstrf.org or to the NICHD Laboratory Specialist (NICHDLabSpecialist@westat.com) with summary of plan for shipment prior to shipping samples to either the BRI or Westat Repositories, respectively. This plan must be approved before proceeding until otherwise notified.
- For labs with IMPAACT PBMCs stored for more than 24 hours at -80 degrees: provide the IMPAACT Lab Center a list of all PBMC PTID visits impacted before shipping specimens to repository.

MTN

- Do not resume shipping of samples without email approval from the MTN Lab Center.
- Sorting of MTN-020 samples to get cryoboxes ready for eventual shipment can be done at the discretion of the laboratory.
- Notify the MTN Lab Center if any COVID related disruptions will affect laboratory inventory or readiness.