**Date:** September 6, 2013

**From:** ACTG and IMPAACT Network Laboratory Leadership: Dr. Robert Coombs, Dr. Susan Fiscus

**Cc:** ACTG/IMPAACT Laboratory Technologist Committee, the ACTG Laboratory Science Group, and IMPAACT Central Laboratory

**To:** ACTG, IMPAACT Laboratories

**Subj**: Refresher for Policies and Procedures regarding LDMS usage

****Please forward this information to the relevant laboratory personnel at your site****

The purpose of this memo is to remind laboratory personnel responsible for conducting ACTG and IMPAACT protocols the importance of key issues when using the LDMS system:

- Utilization of the LDMS is essential to ensure the quality of laboratory data.
- Use of the LDMS ensures proper tracking of results, which is required to support the Networks' abilities to conduct necessary research and comply with Good Clinical Laboratory Practices (GCLP).
- The LDMS helps laboratories to track the quality of specimens necessary for studies conducted by the DAIDS-sponsored clinical trial networks, namely ACTG and IMPAACT.
- Critical factors that affect the quality of specimens include processing time and time to specimen freezing, which are both tracked by the LDMS.
- The LDMS tracks the storage location of each specimen, which allows the Networks and Network researchers to easily locate samples for protocol-specified testing.

## A. Required Use of the LDMS for submitting HIV-1 RNA viral load results:

With reference to the cross-Network memos released January 15, 2009- *Required Use of LDMS for Submitting HIV-1 RNA Viral Load and DNA PCR Results* and September 29, 2011- *Required Use of the VQA 200 copies/ml Control for All ACTG/IMPAACT Viral Load Assays* there are a few key instructions to consider when using the LDMS for HIV-1 RNA results submission for ACTG and IMPAACT protocols:

- All HIV-1 RNA results for ACTG and IMPAACT protocols should be submitted using the LDMS for assay platforms supported by the LDMS.
- The LDMS requires the 200 copies/ml control to be included on any Abbott or Taqman run including ACTG, IMPAACT or VQA specimens. The 200 copies/ml control data can be added to the LDMS prior to resulting an assay in the VQA Kit Entry Module, or on the assay preview tab prior to resulting the run.
    - Testing runs performed without the 200 control require team virologist approval and may require repeat testing with the control added to the assay run.

## B. Mandate for use of LDMS Storage Module

In order to collect the necessary storage information, the ACTG and IMPAACT networks require all laboratories to use the LDMS Storage Module. The Data Management Center(s) works with the Networks to track compliance with this mandate and will query the lab when the module is not being utilized as expected. According to the cross-Network memos dated August 23, 2010- *Mandate for use of LDMS Storage Module and PBMC Processing Tracking Fields* and November 10, 2010 – *Mandate for Use of the LDMS Storage Module*, the following requirements need to be completed in order to maintain the integrity of the specimens:

- All specimen storage locations should be entered into the Storage Module within one week of sample collection or receipt in the laboratory and prior to preparing the LDMS shipping manifest.
- Ensure that the **Temperature** field, as defined in the **Freezer Cfg** (Configuration) tab of the LDMS **Storage Module**, accurately reflects the physical storage temperature; this will allow the Data Management Center to track and confirm storage conditions prior to shipment.

## C. Implementation of LDMS Barcode at ACTG Network Laboratories

Barcoding of specimens at processing laboratories for all sites is required for ACTG and IMPAACT protocols. With reference to the cross-Network memo released August 13, 2008- *ACTG and IMPAACT Bar Coding Implementation,* the steps listed in this section assists with the Networks' mission to ensure proper tracking of specimens:

- After LDMS barcode labels are printed, they must be visually inspected to ensure that the barcode is not cut-off on any side, that all printed items are readable and intact, that no line or crimps affect the barcode or printed items, and that the barcode is not covered by the label tail, either by using a label size with a short tail or by applying the label to the tube tail-first. If the label does not pass inspection, it must be discarded and reprinted, which may involve making printer alignment or configuration adjustments.
- Labels should be scanned to check the quality of the barcode. This can be done by either scanning the specimens to assign storage locations in the LDMS Storage Management module or by scanning the label into any text editor program such as Word or Notepad. The ability to be scanned must be verified for all barcode labeled specimens prior to shipment to the BRI Repository. Labels that are unable to be scanned must be discarded and reprinted, which may involve making printer alignment or configuration adjustments. All labels are visually inspected for quality upon arrival at the central BRI Repository.
- Laboratories should print a set of test labels after printer alignment or calibration, or after changing printer components, such as label stock or ribbons, to verify the scan prior to generating labels for specimen tubes.
- To successfully scan a barcode on a labeled tube:
    - Angle the scanner and make sure there is distance between the scanner and the tube.

- Hold the top of the tube with the thumb and index finger, placing the remaining fingers directly behind the tube to darken the background and provide a contrast while scanning.
- For tubes that do not scan immediately using the technique described above, release the trigger on the scanner and depress it a second time (i.e. a double trigger) or pull the scanner away from the barcode on the tube and then bring it closer while keeping the laser on the barcode.

- For tubes that may have minor smudges or accumulated ice covering the barcode, wipe the tube with gauze immersed in 70% alcohol prior to scanning.

## D. Mandate for use of LDMS Storage Module and PBMC Processing Tracking Fields

In order to collect the necessary PBMC processing and storage information the ACTG and IMPAACT requires all of the succeeding steps to be followed. Please reference the cross-Network memo dated August 23, 2010- *Mandate for use of LDMS Storage Module and PBMC Processing Tracking Fields:*

- The following modules/fields are required for all logged PBMC specimens
  - Specimen Management Module
    - Processing Date
    - Processing Time
    - Processed By Tech Initials
    - Total Cell Count
    - Frozen Time
  - Storage Module

| Module | Button | Field | Notes |
|---|---|---|---|
| Specimen Management | Primary Details | **Processing Date** | **Processing Date** will default to **Specimen Received Date**, but can be modified as appropriate. |
| Specimen Management | Primary Details | **Processing Time** | **Processing Time** is the time when the specimen tube was first opened. You might also think of this as the processing ***start*** time. |
| Specimen Management | Primary Details | **Processed By Tech Initials** | **Processed By Tech Initials** will default to the user logged into Specimen Management, but can be modified as appropriate. |
| Specimen Management | Primary Details | **Total Cell Count** | See section 16.3 of the Cross-Network PBMC Processing SOP (version 2.0 effective July 7, 2009). |
| Specimen Management | Aliquot Details | **Frozen Time** | **Frozen Time** is defined as the time when: The StrataCooler® Cryo or NALGENE® Mr. Frosty is put into the -80°C freezer. The cooling program of the controlled-rate freezer, such as CryoMed®, is started. |

| Module | Button | Field | Notes |
|---|---|---|---|
| **Storage** | All | All | All cryopreserved PBMC specimens should be assigned freezer locations in the **Storage Module** prior to preparing the LDMS shipping file. Ensure the **Temperature** field, as defined in the **Freezer Cfg** (Configuration) tab of the LDMS **Storage Module**, accurately reflects the physical storage temperature. This will allow the Data Management Center to track and confirm storage conditions prior to shipment. |

- **Specimen Collection Date** and **Specimen Collection Time** are already required fields.
- **Total Time** will be calculated from **Specimen Collection Time** and **Frozen Time**; ideally, this is 8 hours or less but all specimens should be processed regardless of the **Total Time.**
- **Total Processing Time** will be calculated from the **Processing Time** and the **Frozen Time**; there are no requirements for **Total Processing Time**, but three hours is a good target.

## E. Additional Informational Memos

Other informational memos relating to ACTG specimen storage and usage include those distributed on May 2, 2008- *Specimen Destruction for ACTG Non-Priority Protocols* and March 3, 2004- *Storage of Specimens Collected for ACTG Protocols Less than ACTG 300*.

To access the all aforementioned memos in their entirety please go to the FSTRF website, https://www.fstrf.org/. Note, login to the FSTRF website is required.

For information on discarding, archiving, and destroying of ACTG or IMPAACT specimens please follow the most current and relevant SOP for instructions.

Please contact the ACTG Laboratory Science group (actglaboratorycoordination@s-3.com), IMPAACT Central Laboratory (impaact.qaqc@fstrf.org) or LDMS User support (ldmshelp@fstrf.org) if you have any questions.