

DATE: August 23, 2010  
TO: PBMC Processing Laboratories  
FROM: ACTG, IMPAACT, HPTN, HVTN and MTN Network Laboratory Leaderships  
SUBJECT: Mandate for use of LDMS Storage Module and PBMC Processing Tracking Fields

### **Purpose**

Quality PBMC specimens are necessary for many of the studies conducted by the DAIDS-sponsored clinical trials networks, including ACTG, IMPAACT, HPTN, HVTN and MTN. Factors that affect the quality of PBMC specimens include processing time and storage conditions. Information as to how each sample is processed and stored allows the networks and network researchers to ensure that the samples are used appropriately.

### **New Requirements**

In order to collect the necessary PBMC processing and storage information, ACTG, IMPAACT, HPTN, HVTN and MTN will require all PBMC processing laboratories to use the following LDMS modules/fields as of **September 13, 2010**.

The following modules/fields will be newly required for all logged PBMC specimens.

- Specimen Management Module
  - **Processing Date**
  - **Processing Time**
  - **Processed By Tech Initials**
  - **Total Cell Count**
  - **Frozen Time**
- Storage Module

Please see important details and notes about each item on the next page.

The Data Management Center will work with the networks to track compliance with this mandate beginning **September 13, 2010** and will query the lab when fields are not completed as expected.

### **Support**

Please contact LDMS User Support with any questions about how to use these required fields/modules:

Phone: (716) 834-0900 Ext. 7311

E-mail: [ldmshelp@fstrf.org](mailto:ldmshelp@fstrf.org)

LDMS User Support hours of operation are Monday through Friday, 12:00am – 6:00pm Eastern Time.

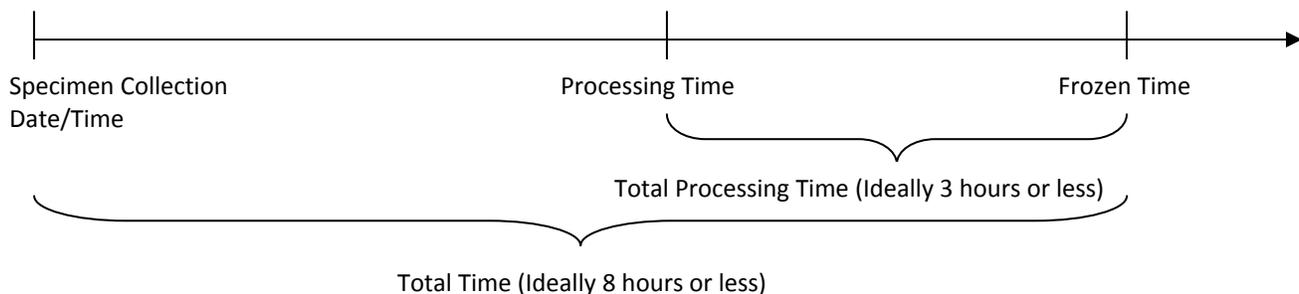
## Newly Required LDMS Modules/Fields

Implementation Date: September 13, 2010

Module	Button	Field	Notes
Specimen Management	Primary Details	<b>Processing Date</b>	<b>Processing Date</b> will default to <b>Specimen Collection Date</b> , but can be modified as appropriate.
Specimen Management	Primary Details	<b>Processing Time</b>	<b>Processing Time</b> is the time when the specimen tube was first opened. You might also think of this as the processing <i>start</i> time.
Specimen Management	Primary Details	<b>Processed By Tech Initials</b>	<b>Processed By Tech Initials</b> will default to the user logged into Specimen Management, but can be modified as appropriate.
Specimen Management	Primary Details	<b>Total Cell Count</b>	See section 16.3 of the Cross-Network PBMC Processing SOP (version 2.0 effective July 7, 2009).
Specimen Management	Aliquot Details	<b>Frozen Time</b>	<b>Frozen Time</b> is defined as the time when: <ul style="list-style-type: none"> <li>The StrataCooler® Cryo or NALGENE® Mr. Frosty is put into the -80°C freezer.</li> <li>The cooling program of the controlled-rate freezer, such as CryoMed®, is started.</li> </ul>
<b>Storage</b>	All	All	All cryopreserved PBMC specimens should be assigned freezer locations in the <b>Storage Module</b> prior to preparing the LDMS shipping file. Ensure the <b>Temperature</b> field, as defined in the <b>Freezer Cfg</b> (Configuration) tab of the LDMS <b>Storage Module</b> , accurately reflects the physical storage temperature. This will allow the Data Management Center to track and confirm storage conditions prior to shipment.

### Other Notes

- **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.



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