



Date: June 23, 2016

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Cc: ACTG/IMPAACT Laboratory Technologist Committee, ACTG Laboratory Science Group, FSTRF/DMC

To: ACTG Laboratories

Subj: LDMS Usage Update for Policies and Procedures – Submitting assay results

****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 protocols the importance of key issues when using the LDMS system, specifically in reporting assay results:

- 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 has recently expanded to support tuberculosis assays (GeneXpert MTB RIF)**

It is the expectation of the ACTG Network Laboratory Center that ACTG laboratories use the LDMS to report results for all supported assays. Current LDMS supported assays include: HIV-1 RNA PCR (viral load testing), DNA testing, Pharmacology (PK), HCV viral load testing, and GeneXpert TB testing.

- Abbott RealTime HIV-1 Test
- COBAS TaqMan HIV-1 Test
- COBAS TaqMan HCV Test
- COBAS TaqMan HIV-1 Qualitative Test
- PK Assay
- Xpert MTB-RIF Assay

Additional information on using the LDMS for all supported assays can be found online in the LDMS user manual available on the LDMS public website (www.ldms.org).

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