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The purpose of a consensus method is to help standardize assay performance across laboratories. Importantly, when available, standardized assay methods minimize variability and allow for the comparison of results across laboratories both domestic and international. Method standardization is a critical function of the clinical laboratory where data are used to monitor and treat patients. While the results obtained in the clinical setting are standardized against “expected” (normal) values, the results obtained in a clinical research laboratory may be less well defined. Therefore, the clinician and clinical researcher must be both assured that deviations from expected results reflect true changes due to a therapeutic intervention or disease progression (or both) and are not due to unappreciated variations in the testing method.

In 1993, 1997 and again in 2005, laboratory method documents used by the Adult and Pediatric AIDS Clinical Trials Group (ACTG and PACTG, respectively) were compiled into a Virology Manual. This manual has been since updated by the ACTG and International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) group Laboratory Technologist Committee (LTC) to reflect current laboratory practices, as well as general specimen processing, shipping and repository guidelines that pertain to the ACTG/IMPAACT Network Virology, Immunology and Pharmacology Laboratories. As a consequence, this manual has been renamed the *ACTG/IMPAACT Laboratory Manual of Assay and Operational Procedures*.

In an effort to make *the Manual* applicable to others who work in HIV/AIDS laboratories, *the Manual* was extensively revised in keeping with the guidelines recommended by the Clinical Laboratory Improvement Act (CLIA) and the DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards (November 14, 2008)

The Manual will provide an easily accessible reference for both domestic and international laboratories, and will help ensure standardized handling of specimens collected for ACTG and IMPAACT clinical trial protocols.

The Manual is available electronically through the HANC website at <http://www.hanc.info/labs/Pages/ACTGIMPAACTLabManual.aspx>. Updates and revisions to the *Manual* will be made as necessary, distributed to the laboratories by e-mail, and posted on the HANC website.

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