



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
DIVISION OF RETROVIROLOGY
13 TAFT CT, SUITE 100
ROCKVILLE, MD 20850

MCMR-UWA-E

30 May 2007

MEMORANDUM FOR All Laboratory Directors and Managers, supported by the HIV Diagnostics and Reference Laboratory (HDRL), Rockville, MD 20850

SUBJECT: Changes to the Submission Guideline version May 2007

1. This memorandum is intended to summarize the major changes to the HDRL Submission Guideline version Jan 07. The new submission guideline and forms will also be available on the HDRL website <http://www.hivresearch.org/hivdiagnostics/index.html>.
2. Summary of major changes:
 - a. Change and addition of laboratory forms. The new forms can be found in the attachments section of the guideline and individualized on the Website.
 - b. HIV-1, HIV-2, HTLV I/II DNA-PCR analysis will no longer be handled by the HDRL. For these assays the individual laboratories should contact Quest Diagnostics for specimen and assay requirements.
 - c. The HTLV Western Blot assay will no longer be available for clinical testing. This assay is not FDA approved and may only be requested by the Blood Donor Centers if required. The results of the HTLV I/II EIA will serve for the HDRL final interpretation, the WB will serve only for informational purposes.
 - d. The non-FDA approved HIV-2 Western Blot will no longer be available from the HDRL. If a diagnosis of HIV-2 is suspected, contact the HDRL Laboratory Manager.
 - e. The addition of section 5.0, Follow-up Procedures for HIV Positive and Indeterminate Results. This is a new section of the document and a separate SOP (HDRL GEN 002) has been developed in order to meet this new standard required by the College of American Pathologists. Please refer to the SOP for additional guidance. This document is available on the HDRL website.
 - f. IAW CAP GEN 40530, Sites are **REQUIRED** to send by Fax:
 1. A tracking and/or invoice number provided by the shipping company to ensure that all shipments that are sent to the HIV Diagnostics and Reference Laboratory are received.

2. Transmittal, inventory or batch list of the specimens contained within the shipment to allow for verification of that the specimens sent were received by the HDRL.
- g. With the release of this version of the submission guideline the HDRL will begin strict enforcement of the specimen rejection criteria in section 2.9. Previously we have been more lenient in our enforcement but we continue to see missing information. Please note CLIA regulations require physician information when requesting high complexity tests.
3. Additional changes may be found in the submission guideline. Please review for assay requirements prior to shipment.
4. POC for this memorandum is CPT Kurt N. Martin (commercial) 301-251-5003, CPT Alfred Nader (commercial) 301-251-8382, or the undersigned at (commercial) 301-251-8346.



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