



# Summary of the National Public Health Laboratory HIV Algorithm Conference Call

August 19, 2009

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**Background:** The criteria for confirmation of HIV infection have remained unchanged since their establishment in 1989 by the Centers for Disease Control (CDC) and the Association of State and Territorial Public Health Laboratory Directors (now APHL). Updating the HIV testing algorithm to incorporate current technologies is a high priority for the APHL/CDC HIV Steering Committee.

In August of 2006, the APHL/CDC HIV Steering Committee formed two multi-disciplinary workgroups to develop optimal testing strategies for use in the laboratory and at the point of care (POC). At the 2007 HIV Diagnostics Conference, researchers presented data that evaluated these proposed algorithms. Based on these findings and other research, a summary report was developed on the status of the proposed algorithms. [“HIV Testing Algorithms: A Status Report”](#), issued in April of 2009, thoroughly describes the proposed testing strategies, examines available data in support of the proposals and outlines specific data that is still needed to evaluate the algorithms.

In order to bring attention to these additional data needs and inform APHL members of the status of proposed HIV testing algorithms, APHL convened this national conference call. The presentation can be found on APHL’s website:

<http://www.aphl.org/aphlprograms/infectious/hiv/Documents/NationalPHLAlgorithmCall.pdf>.

- Dr. Michael Pentella, PhD, D(ABMM), University of Iowa Hygienic Laboratory and chair of the APHL/CDC HIV Steering Committee, introduced the speakers for the conference call and welcomed the participants. Dr. Barbara Werner, PhD, Massachusetts Department of Public Health, then provided an overview of the work that led to the publication of “HIV Testing Algorithms: A Status Report.” Dr. Werner pointed out that, despite improvements in technology and the introduction of point-of-care testing, the consensus algorithm for HIV diagnosis has remained unchanged since 1989. In order to achieve a “menu of options” for HIV diagnosis, additional data is needed. Dr. Werner encouraged call participants to complete the ongoing APHL member survey of HIV testing practices, read the Status Report and review the data needs outlined therein. Participants were also encouraged to share relevant data with APHL staff via [e-mail](#), and to consider submitting an abstract for the [2010 HIV Diagnostics Conference](#).
- Berry Bennett, MPH, Florida Bureau of Laboratories, outlined several examples of the types of data the HIV Steering Committee is interested in collecting. To highlight one of the data needs in particular, Mr. Bennett introduced a [data template](#) for the collection of signal-to-cutoff ratios for specimens *repeatedly* screened via immunoassay. Obtaining this data will contribute significantly to the HIV Steering Committee’s ultimate goal of developing new HIV testing guidelines that will provide more rapid, accurate and cost-effective options for the diagnosis of HIV. Additional sources of data mentioned by Mr. Bennett included the following:
  - Readily available data from retrospective studies or parallel methodology evaluations
  - Prospective studies based on the schematics and data needs outlined in the Status Report
  - Comparative performance data as a result of routine laboratory operations

- Mr. Bennett went on to present a model study conducted in Florida for the evaluation of the Dual Immunoassay Algorithm (Laboratory Algorithm 3 in the Status Report). He outlined the aspects of the study design important for such a validation and presented a performance comparison between this new algorithm and the traditional testing algorithm. Mr. Bennett pointed out that the Dual Immunoassay Algorithm could have significant benefits over the current testing algorithm in both cost-per-test and sensitivity during seroconversion.
- Dr. S. Michele Owen, PhD, Centers for Disease Control and Prevention, then announced the establishment of a specimen repository at CDC for unique or difficult to resolve specimen types. CDC is requesting specimens (serum, plasma, dried blood spot) for this repository to aid in the evaluation of new technologies and the collection of data for the proposed algorithms. Participants on the conference call were urged to express their interest in contributing to the repository to Dr. Owen ([smo2@cdc.gov](mailto:smo2@cdc.gov)) or Steven Ethridge ([sfel@cdc.gov](mailto:sfel@cdc.gov)) by November 1, 2009. Specimen types of interest include:
  - Discordant results on two or more FDA-approved/licensed tests
  - Serology-positive, NAT-negative
  - NAT-positive, serology-negative
  - Screening-positive, WB/IFA-indeterminate or negative (preferably with follow-up data)
  - Known or suspected HIV-2-positive specimens
  - Known or suspected non-B subtype specimens
- A total of sixty-nine parties participated in the call.
- Question and Answer Session
  - Q: Will laboratories have access to specimens in the CDC repository?
  - A: Yes, if the volume of the specimen is sufficient. Laboratories that submitted specimens will have priority access to the repository. [Note: To be eligible for the repository, specimens are required to have a minimum volume of 1mL.]
  - Q: Is CDC interested in collecting oral fluid specimens for the repository?
  - A: Oral fluid specimens would probably not meet the volume criteria for desired specimens, but CDC is still potentially interested. Please contact Dr. Owen if you have oral fluid specimens you would be interested in submitting.
- Call participants were reminded again to complete the member survey on HIV testing practices and to review the call for abstracts for the 2010 HIV Diagnostics Conference. They were also reminded that the “HIV Testing Algorithms: A Status Report” document contains a complete list of data needed to evaluate the proposed HIV testing algorithms.