Abstract #38

Validation of a New 'Universal' Control Material for Use with Multiple CLIA-Waived Rapid HIV Antibody Tests Use for Point-of-Care Testing

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ISSUES

Since November 2003, 3 HIV rapid tests have received FDA approval and a waiver of requirements specified for laboratory testing under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, allowing for their use outside of traditional laboratory settings. As more of these point-of-care tests (POCTs) have become available, some CLIA-waived test sites have chosen to offer multiple POCTs. CLIA does not require quality assurance (QA) for waived tests; only that sites follow the tests package insert (PI). CDC has developed QA guidelines for HIV rapid testing, but only for individual tests. However, each test kit has unique specifications for test kit and control product storage and usage, and several PIs are restrictive as to what materials may be used for QA purposes. A universal external control for all POCTs would allow for an efficient QA program to be implemented at sites using multiple tests.

PROJECT

To validate the performance of a universal external control with rapid HIV testing, the Xsera™ HIV-1/2 Antibody Controls were run with 3 different CLIA-waived rapid HIV antibody tests: the OraQuick Advance HIV-1/2 Rapid HIV Antibody Test, Clearview Stat-Pak HIV-1/2 Assay, and Uni-Gold Recombigen HIV. Each rapid test was used 300 times with Xsera control specimens (100 each of HIV negative, HIV-1 positive, and HIV-2 positive), along with manufacturer-specific controls (3 controls (HIV-1, HIV-2 and HIV negative) for OraQuick and Clearview Stat-Pak; 2 controls (HIV-1 and HIV Negative) for Uni-Gold), for a total of 908 tests. Subjective determinations of color intensity were made for all reactive tests. This validation activity was performed by non-laboratorians in a CLIA-waived setting at the San Francisco Department of Public Health AIDS Office (SFDPH.)

RESULTS

All 908 control tests produced the expected results, validating the performance of Xsera controls with the OraQuick Advance, Clearview Stat-Pak and Uni-Gold tests. Compared to the Oraquick Advance kit control materials, the Xsera controls produced slightly darker reactions with the test antigen. The Unigold and Clearview HIV control materials produced reactions of similar intensity to those produced by the Xsera materials on their respective tests.

LESSONS LEARNED

After completing this validation, the SFDPH has begun using the Xsera control materials as part of their QA program. The Xsera controls have simplified the logistics of QA program implementation for agencies, increasing the likelihood they will be able to maintain laboratory best practices, and allowing them to successfully provide HIV POCT with multiple different rapid HIV tests. However, some rapid test PIs still require use of the manufacturers controls in specific instances (e.g. upon receipt of a new kit lot.) CLIA-waived HIV test sites may have difficulty implementing this protocol unless PIs can be modified to allow for the use of unassayed HIV-1 and HIV-2 controls commercially available for use with multiple different rapid tests as part of a validated QA plan.