

## ACM Medical Laboratory Changes to HIV Confirmatory Testing

**ACM will be discontinuing the western blot assay effective 11/10/14. The test will be replaced with an HIV differentiation assay.** HIV-1/HIV-2 antibody differentiation assays is considered to be more sensitive for identifying patients with acute HIV infection because they tend to detect antibodies earlier than the Western blot. These immunoassays not only detect HIV-1 and HIV-2 antibodies, but can also differentiate between them. This can have important treatment implications, as HIV-2 does not respond to some antiretroviral agents. Results are interpreted as reactive for HIV-1, reactive for HIV-2, reactive for HIV (non-differentiated), or nonreactive.

The current HIV diagnostic algorithm consists of a repeatedly reactive immunoassay (IA), followed by a supplemental test, such as the Western blot (WB) or indirect immunofluorescence assay (IFA). Because current laboratory IAs detect HIV infection earlier than supplemental tests, reactive IA results and negative supplemental test results very early in the course of HIV infection have been erroneously interpreted as negative. The current laboratory diagnostic algorithm for HIV cannot detect acute infections and misclassifies approximately 60% of HIV-2 infections as HIV-1, based on HIV-1 WB results (4). To address this problem, the Centers for Disease Control and Prevention (CDC) has proposed an alternative HIV testing algorithm designed to 1) detect acute infections more often; 2) reduce the frequency of indeterminate results on supplemental testing; and 3) differentiate HIV-1 and HIV-2 antibodies. This algorithm has been reported to have high sensitivity (>99.7%) and specificity (100%) and has been adopted by the Clinical Laboratory Standards Institute (CLSI).<sup>7</sup>

### Alternative Testing Algorithm

The new diagnostic algorithm (see page 2) replaces the WB with an HIV-1/HIV-2 antibody differentiation assay as the supplemental test and includes an RNA test to resolve reactive IA with negative supplemental test results. In retrospective studies, this algorithm performed better than the WB at identifying HIV-antibody-positive persons, detecting acute HIV-1 infections, and diagnosing unsuspected HIV-2 infections.

ACM Test Code: 0198

Recommended CPT Codes: 86701, 86702

LOINC Codes: 29893-5 (HIV-1), 30361-0 (HIV-2)

## New HIV Test Confirmation Algorithm

