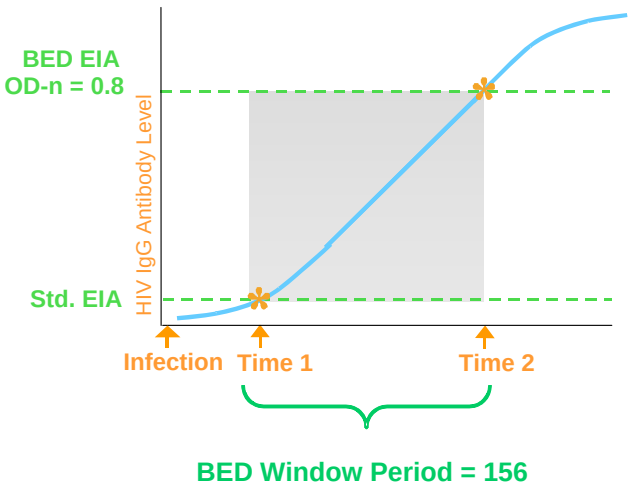
HIV Incidence Surveillance in Texas
- Introduction for Commercial Laboratories -

In June 2005 the Texas Department of State Health Services (DSHS), in collaboration with the Centers for Disease Control and Prevention (CDC), began an exciting new surveillance activity called HIV Incidence Surveillance that will provide a more complete and current picture of the HIV epidemic. Until recently, the HIV surveillance system in Texas and the United States has depended upon diagnostic tests that do not distinguish between recent and long-standing infections. To be most effective, HIV prevention programs need to know who was recently infected as well as those who obtained a positive test result. As echoed in the Institute of Medicine (IOM) 2001 report, *No Time to Lose—Getting More from HIV Prevention, "*…to more effectively direct prevention interventions to communities at risk, the Committee recommends that…CDC create a surveillance system that can provide national population-based estimates of HIV incidence." The goal of HIV Incidence Surveillance is to produce local and national estimates of the number of HIV infections acquired within the past year, including those undiagnosed.

HIV Incidence and Advanced HIV Testing Technologies

Advances in laboratory science are now available to complement the diagnostic EIA and Western blot tests. CDC has developed a new HIV testing technology called the BED HIV-1 Capture EIA (BED) assay that is able to distinguish recent versus long-standing infections in persons with a confirmed positive test. This new test measures the proportion of HIV antibodies among all IgG antibodies in the serum that increases as the body responds to infection as depicted in Figure 1.

Figure 1. Window Period and the BED Assay (Source: CDC)



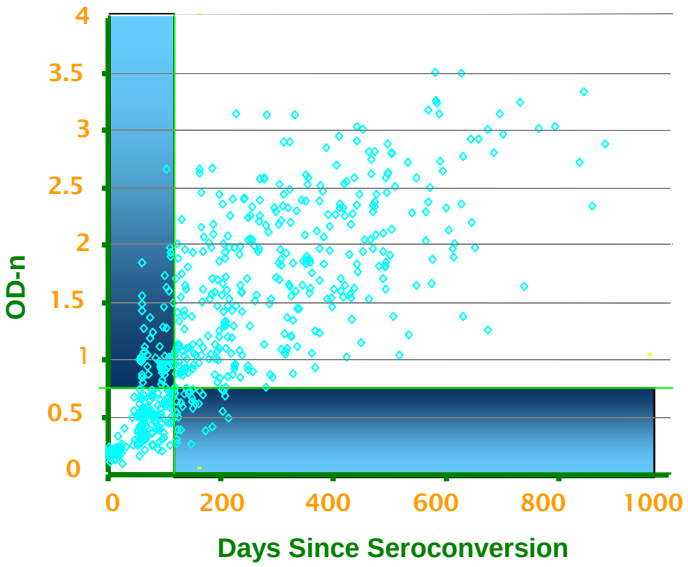
As the time from infection increases (X Axis), levels of HIV-specific IgG antibody in the blood increase (Y axis). The standard EIA or Western blot will detect HIV antibodies in a person tested at Time 1 or later in the course of infection. When a normalized optical density (OD-n) cutoff for the BED assay is set at 0.8 (optimal for incidence estimates), a person tested prior to Time 2 (when levels of HIV-specific antibodies are low) would have a non-reactive result on the BED assay. Because the BED assay is only performed on confirmed positive specimens, a non-reactive BED result would indicate a recent infection. The time when a person tests positive on the standard EIA until the time when the proportion of HIV antibodies in their serum reaches a predetermined OD-n cutoff on the BED assay is defined as the BED window period. The length of

the window period depends on the OD-n cutoff used to distinguish a reactive from a non-reactive specimen. Using an OD-n cutoff of 0.8, the average BED window period for use with multiple HIV subtypes is approximately 156 days.

BED Assay Results and the Individual

The BED assay is approved by the Food and Drug Administration (FDA) for surveillance use only and is restricted from being used for diagnostic or clinical purposes. Because the BED assay has no clinical value for the individual patient, results will not be returned to the individual or the lab that conducts the initial EIA/Western blot. It is known to misclassify individual samples as recently infected due to: 1) the variability among individual antibody responses to infection; 2) low antibody levels in persons with advanced HIV disease; and 3) persons on antiretroviral therapy.

Figure 2. BED: Changes in OD-n After Seroconversion (Source: CDC)



As shown in Figure 2, the BED assay misclassifies individual infections as recent or long-standing infection at similar rates, which allows the resulting population-level data to be useful for population estimates even though test results are not meaningful for individuals. The Institutional Review Boards (IRB) of both the CDC and DSHS have classified Incidence Surveillance as non-research, and it is a permitted disclosure under HIPAA §164.512 (b), public health activities.

Conclusion

As the HIV epidemic continues to evolve, we must complement advances in diagnostics and treatments with new epidemiologic and testing methods. DSHS requests your active participation in this endeavor to track the leading edge of the HIV epidemic. No additional testing at your laboratory is needed. BED EIA testing is conducted at the CDC-designated BED testing laboratory in Wadsworth New York on remnants of specimens that you have confirmed to be HIV-positive through routine testing. DSHS can offset the costs of shipping and supplies that are involved in submitting specimens to the BED testing lab. We look forward to collaborating with you and your colleagues throughout the State in this effort to better characterize the epidemic and improve our efforts to prevent HIV transmission.