HIV-1 RNA Qualitative Assay Approval

The Food and Drug Administration (FDA) announced the approval, on October 5, 2006, of the APTIMA(r) HIV-1 RNA Qualitative Assay, manufactured by Gen-Probe Incorporated of San Diego, California, for use in clinical laboratories and public health facilities to detect primary (early) HIV-1 infection.

The APTIMA~ HIV-I RNA Qualitative Assay is an in vitro nucleic acid test (NAT) for the detection of human immunodeficiency virus (HIV-1) in human plasma intended for use as an aid in the diagnosis of HIV-I infection, including acute or primary infection, before the appearance of antibodies to HIV-1.

Traditional detection and diagnosis of HIV-I infection is based on testing for anti-viral antibodies by enzyme immunoassay (EIA) with confirmation by supplemental antibody tests such as Western blot or immunofluorescence assays (IFA). Although sensitivity of HIV-1 antibody detection has increased in the last few years, a window period between infection and detectable serological markers still exists. Following a recent exposure to HIV-I, it may take several months for the antibody response to reach detectable levels, during which time, testing for antibodies to HIV-I, including the use of rapid antibody tests, will not indicate true infection status.

The newly approved test may provide earlier diagnosis of infection because it detects nucleic acid of the human immunodeficiency virus (HIV-1) in human plasma, rather than the antibody response to the virus. Presence of HIV-I RNA in the plasma of patients without antibodies to HIV-I is indicative of acute or primary HIV-1 infection.

The test, however, is not meant to be used as a stand-alone test for the diagnosis of HIV-1 infection. A positive nucleic acid test should be viewed as a unconfirmed test result, indicating probable infection, and should be followed up later with traditional EIA antibody testing to confirm infection with the Human Immunodeficiency Virus.

In addition, the APTIMA HIV-1 RNA Qualitative Assay may be used as an additional test to confirm HIV-I infection in an individual whose specimen is repeatedly reactive for HIV-1 antibodies. This is important because the Western blot can, in some instances, be difficult to interpret and may not always provide a conclusive result. The APTIMA test can be used instead of the traditional Western blot test or IFA for confirmation of HIV-1 infection when the screening test result for HIV-1 antibodies is positive.

The sensitivity of the APTIMA(r) HIV-1 RNA Qualitative Assay is comparable to that of FDA approved viral load assays that measure the amount of HIV-1 virus circulating in the blood of patients with established HIV-1 infection to monitor the treatment and progression of AIDS. Unlike the viral load tests, however, the APTIMA test has been approved for the diagnosis of primary HIV-1 infection, as well as for confirming HIV-1 infection when tests for antibodies to HIV-1 are positive.

The product labeling for this test will be available soon on the list of FDA Licensed / Approved HIV, HTLV and Hepatitis Tests on the FDA web site.

Richard Klein

Office of Special Health Issues
Food and Drug Administration

An archive of past list serve announcements is available on the FDA web site at
http://www.fda.gov/oashi/aids/listserve/archive.html