Urine-Based Test to Detect HIV Antibodies

The U.S. Food and Drug Administration has approved the urine-based HIV-1 Western Blot test that confirms the presence of antibodies to human immunodeficiency virus (HIV) in urine samples.

Clinical trials of persons who were at low-risk for HIV infection were conducted to determine the specificity of the test. Blood serum and urine samples were tested, and results were compared. The results showed that the specificity was 100 percent (515 out of 515). To determine the sensitivity of the test, another study was conducted with persons known to be HIV positive by blood tests. Results showed that the sensitivity of the test was 99.7 percent (746 out of 748). The two urine samples that had negative results on the Western Blot test were from seropositive individuals who had acquired immunodeficiency syndrome and were receiving anti-retroviral therapy.

According to the manufacturer, the urine HIV test system reduces costs because urine requires no specialized collection devices, means of handling or disposal system, or trained medical personnel for sample collection. Samples require no preservation and are stable for 55 days at room temperature. More information about the test can be obtained by calling 800-428-4007 (ext. 2957) or 510-526-2541.