



SAN LUIS OBISPO COUNTY *Messenger* Public Health Laboratory

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HIV Testing – 4th generation serum testing

The face of HIV infection has changed greatly since the early years of the epidemic. Infected individuals are now routinely living for decades with the help of daily medication. But new infections continue to occur at an alarming rate, with about 40,000-50,000 new cases annually in the U.S. While many infected persons unfortunately do not get tested at all, new testing methodology has become available to shorten the window between HIV infection and lab detection of HIV for persons who want that information.

The so-called 4th generation serum antibody test was introduced by the San Luis Obispo County Public Health Laboratory (SLOPHL) in February. This test can detect HIV antibody against both HIV Type 1 or Type 2 viruses, and HIV1 p24 antigen, if present, well before any rapid test or previous generation of HIV blood test. This 4th generation HIV serum test has reduced detection of infection to about 14-18 days, bested only by the ability to detect HIV-1 ribonucleic acid (RNA) at about 9-11 days. This 4th generation HIV carries the following qualifier message:

NON-REACTIVE TEST RESULT INDICATES NON-DETECTION OF HIV-1 (M AND O GROUPS) ANTIBODY, HIV-1 P24 ANTIGEN AND HIV-2 ANTIBODY.

The new algorithm that SLOPHL uses allows rapid screening for HIV-1, HIV-2 plus P24 antigen, followed by supplemental testing with HIV-1 indirect fluorescent antibody (IFA). Most cases can be confirmed on the same day that the screening assay is performed. In the rare event that indeterminate results are obtained with the supplemental IFA test, the serum specimen is referred by overnight package delivery to the Florida Public Health Laboratory in Jacksonville for HIV-1 RNA qualitative testing. This no-fee referral practice has allowed next-day confirmation of HIV infection twice in the past year. Definitive diagnosis of early stage infection, many times within two-weeks of exposure, is not possible with any other method. For example, the HIV-1 Western blot, a mainstay supplemental test for the past three decades, typically provides confirmation of HIV infection at 30-35 days after exposure. Also screening with the 4th generation test is recommended before the HIV prophylaxis drug Truvada can be administered.

The SLOPHL does continue to provide oral fluid testing by an FDA-approved HIV-1 screening method, a distinct advantage for individuals who might refuse blood collection by venipuncture. In situations where such a screen is positive or indeterminate, rather than wait an additional 2-3 weeks for a Western blot, the client can now opt for serum HIV testing to get a quicker response from the new 4th generation test.

<http://www.cdc.gov/hiv/pdf/hivtestingalgorithmrecommendation-final.pdf>