PROTECTIVE LIFE INSURANCE COMPANY
P.O. Box 830619
Birmingham, AL 35283-0619

HIV TESTING PROTOCOL

HIV TEST FOR SCREENING AND DIAGNOSIS:

As HIV testing technology progresses and the District of Columbia Department of Health updates its recommendations, the Department of Insurance, Securities and Banking reserves its right to modify its minimum standard for testing protocols. Insurance issuers paying for the administration of the test must comply accordingly with the Department's minimum standards.

There are three types of HIV diagnostic tests: antibody tests, antigen/antibody tests, and nucleic acid (RNA) tests. Antibody tests detect antibodies, proteins that your body makes against HIV, not HIV itself. Antigen tests and RNA tests detect HIV directly.

The current testing protocol required in the District of Columbia is as follows:

Initial Test: Tests for HIV shall be conducted with an FDA-approved antigen/antibody combination (4th generation) immunoassay[1] that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to screen for established infection with HIV-1 or HIV-2 and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.

> ***Rationale:*** Initial testing with a 4th generation antigen/antibody combination immunoassay detects more acute HIV-1 infections than initial testing with a 3rd generation antibody immunoassay and identifies comparable numbers of established HIV-1 and HIV-2 infections, with comparable specificity.

Blood tests can detect HIV infection sooner after exposure than oral fluid tests because the level of antibody in blood is higher than it is in oral fluid. Likewise, antigen/antibody and RNA tests detect infection in blood before antibody tests. Some newer antigen/antibody lab tests can sometimes find HIV as soon as 3 weeks after exposure to the virus. No antigen/antibody or RNA tests are available for oral fluid.

Follow-up Testing: HIV tests are generally very accurate, but follow-up testing allows you and your health care provider to be sure the diagnosis is right. Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV-1 and HIV-2 antibodies, undifferentiated.

> ***Rationale:*** Use of the HIV-1/HIV-2 antibody differentiation assay after a reactive initial 4th generation HIV-1/HIV-2 antibody immunoassay detects HIV-1 antibodies earlier than the HIV-1 Western blot, reduces indeterminate results, and identifies HIV-2 infections. Turnaround time for test results is shorter and the cost is lower for the HIV-1/HIV-2 antibody differentiation assay compared with the HIV-1 Western blot. Available evidence is insufficient to recommend specific additional testing, without clinical follow-up, for specimens that are dually reactive for HIV-1 and HIV-2 antibodies on the differentiation immunoassay.

PROPORTION OF FALSE POSITIVE RESULTS EXPECTED:

According to the Centers for Disease Control and Prevention clinical data submitted by the manufacturers of Human Immunodeficiency Virus (HIV) antibody tests to the Food and Drug Administration (FDA) for licensure indicate that sensitivity and specificity of tests currently marketed in the United States are greater than 99%.

All blood, oral fluid and protocols licensed by the FDA follow the same test algorithm: specimens are tested singly by either a screening enzyme immunoassay or a 4th generation antigen/antibody combination assay, and if found reactive are retested in duplicate. If either duplicate is reactive, the specimen is considered repeatedly reactive and is submitted for further testing using either a FDA approved multi-spot test or an HIV-1/HIV-2 antibody differentiation immunoassay. Specimens found reactive by this second test are reported as positive for HIV antibodies. Although a positive result indicates infection with HIV, a diagnosis of Acquired Immunodeficiency Syndrome (AIDS) can only be made clinically if a person meets the case definition of AIDS established by the Centers for Disease Control and Prevention[1].

Data from multiple studies on 4th generation HIV tests demonstrated an overall sensitivity of 99.9-100%. Thus, the achievable false-positive rate of sequentially performed 4th generation tests can be less than 0.1% or less than 1/1,000 persons tested.

DISCLOSURE:
Reference material provided in this notice and consent form is for information purposes only. Applicants for insurance who have questions should seek guidance from a professional health provider.

HIV TESTING COUNSELING REFERRALS:
The DC Department of Health (DOH) HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA) has prepared a comprehensive and easy-to-read directory of all DC HIV/AIDS services, most are funded by the District of Columbia Government. The directory contains information ranging from HIV testing locations to medical care, medications and support services, including nutrition services and housing. A special on-line version can be accessed below.

Directory of HIV/AIDS Services in the District of Columbia and Surrounding Areas
(http://haadirectory.doh.dc.gov/)

For a printable list of primary care sites in DC, compiled by the DOH Primary Care Bureau visit them at the link below.

Primary Care Bureau
(http://doh.dc.gov/page/primary-care-bureau)

The DC Primary Care Association (DCPCA) is a non-profit health equity and advocacy organization dedicated to improving the health of DC's vulnerable residents by ensuring access to high quality primary health care, regardless of an ability to pay. They work to ensure that all residents of Washington, DC have the ability and opportunity to lead healthier lives – through increased health care coverage, expanded access, improved quality, workforce development, and enhanced communication. Members of the DCPCA currently include 15 community health centers and community-based organizations located in the District of Columbia and the Maryland suburbs. Between them, member health centers own and operate nearly 60 health care delivery sites that serve approximately 200,000 residents, most of which offer HIV counseling and testing. A listing of health center locations can be found below.

DCPCA Find a Health Center
(http://www.dcpca.org/find-a-health-center)

[1] *Exception: As of April 2014, data are insufficient to recommend use of the FDA-approved single-use rapid HIV-1/ HIV-2 antigen/antibody combination immunoassay as the initial assay in the algorithm.*