Protective Life Insurance Company
P.O. Box 830619, Birmingham, AL 35283-0619

AIDS TESTING PROTOCOL

An individual shall be considered as having been exposed to the Human Immunodeficiency Virus (HIV) if they test positive in both enzyme immunoassay and a Western Blot assay.

DEFINITIONS

Enzyme Immunoassay (EIA) means a test licensed by the Federal Food and Drug Administration conducted in accordance with the manufacturer's specifications. EIA tests for examination of serum or plasma, oral fluid, or urine are licensed by the Food and Drug Administration. The EIA must be performed by a laboratory licensed by the U.S. Department of Health and Human Services (or by an equivalent state Department of Health) and enrolled in an approved proficiency evaluation program.

EIA Interpretation: a single test of a specimen found non-reactive is reported as negative for HIV infection and no further tests are indicated. A test found reactive is repeated on the same specimen in duplicate, if either of the two duplicates is found reactive the specimen is referred for Western Blot assay.

Western Blot Assay (WB) means an assay licensed by the Food and Drug Administration conducted in accordance with the manufacturer's specifications. WB tests for examination of serum or plasma, or oral fluid, or urine are licensed by the Food and Drug Administration. The WB must be performed on the same specimen found reactive in the EIA by a laboratory licensed by the U.S. Department of Health and Human Services (or by an equivalent state Department of Health) and enrolled in an approved proficiency evaluation program.

WB Interpretation: criteria for **positive** serum or plasma, oral fluid, or urine WB tests are established by the FDA in consultation with the Federal Centers for Disease Control and the Association of State and Territorial Public Health Laboratory Directors. Tests with no WB antibody to HIV are reported as **negative**. Tests with the antibodies which do not meet the criteria for positive are reported as **Indeterminate** Indeterminate findings require follow-up medical and laboratory examinations.

PROPORTION OF FALSE POSITIVE RESULTS EXPECTED WITH THIS PROTOCOL

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 urine protocols licensed by the FDA follow the same test algorithm: specimens are tested singly by Enzyme Immunoassay (EIA) and if found reactive are retested in duplicate. If either duplicate is reactive, the specimen is considered repeatedly reactive and is submitted for Western Blot (WB) test. Specimens found reactive by WB are reported as positive for HIV antibodies. Although a positive WB 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 show that the specificity of this EIA-WB test algorithm in a population of low prevalence is equal to, or greater than, 99.9%[(2)]. Thus the achievable false-positive rate of sequentially performed EIA-WB tests can be less than 0.1% or less than 1/1,000 persons tested.

REFERENCES

1. Centers for Disease Control. (1992). 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. Mortality and Morbidity Weekly Report, Volume 41:RR-17.

2. Centers for Disease Control. (1989). Interpretation and use of Western Blot assay for serodiagnosis of Human Immunodeficiency Virus Type 1 infections. Morbidity and Mortality Weekly Report, Volume 38:S-7.

HIV ANTIBODY TESTING COUNSELING REFERRALS

Clinica Pueblo 1470 Irving Street, NW Washington, D.C. 20010 462-4788	Anonymous Comprehensive pre and post-test counseling Free Walk-in and appointments Results in 10 days
Planned Parenthood 1108 16th Street, NW Washington, D.C. 20036 347-8512	Anonymous Comprehensive pre and post-test counseling $40 Appointment required Results in 73 hours to 1 week
Southwest Health Center 850 Delaware Avenue, SW Washington, D.C. 20024 727-3611	Anonymous Counseling is by a physician or a counselor Walk-in and appointments Results in 2 weeks
Washington Free Clinic 1525 Newton Street, NW Washington, D.C. 20010 667-1106	Anonymous Comprehensive pre and post-test counseling Free Walk-in and appointments Results in 1 week
Whitman-Walker Clinic 1407 S Street, NW Washington, D.C. 20009 332-5295	Anonymous Comprehensive pre and post-test counseling, as well as short-term (up to 8 sessions). Crisis intervention oriented post-test counseling. Free, although donation requested. Appointment required. Results in 48 hours or 1 week (depending on appointment schedule).