

## **AIDS TESTING PROTOCOL**

**A photocopy of this form will be as valid as the original.**

An individual shall be considered as testing positive to exposure to the probable causative agent of AIDS and HIV infection if they have both a positive ELISA test and a reactive Western blot assay.

### **Definitions:**

"Positive ELISA test" means an ELISA test licensed by the federal Food and Drug Administration, performed in accordance with the manufacturer's specifications by a laboratory licensed by the U.S. Department of Health and Human Services, Health Care Financing Administration and a participant in an approved proficiency testing program, and resulting in a single serum or plasma specimen which is reactive, both on an initial testing and on an additional test of the same specimen.(1)

"Reactive Western blot assay" means a Western blot assay test licensed by the federal Food and Drug Administration, performed in accordance with the manufacturer's specifications by a laboratory licensed by the U.S. Department of Health and Human Services, Health Care Financing Administration and a participant in an approved proficiency testing program, and resulting in a demonstration of antibody to the following proteins: p24, p31 and either gp41 or gp160. (1)

### **Proportion of false positive results expected with this testing protocol:**

According to the Centers for Disease Control "clinical data submitted by the manufacturers to FDA (Food and Drug Administration for licensure indicate that the sensitivity of EIA tests currently marketed in the United States are >99%." There are less than 1% false positive with these tests.

"Repeating each initially reactive EIA test increases the specificity of the test sequence by reducing the possibility that technical laboratory error caused the reactive result. In the American Red Cross Blood Services laboratories, a specificity of approximately 99.8% has been consistently achieved during screening of donated blood. However, in a population with a low prevalence of infection, even a specificity of 99.8% does not provide the desired predictive value for a positive test. For this reason, it is particularly important not to rely solely on EIA. Test results should be validated with an independent supplemental test of high specificity conducted by a laboratory with high performance standards. In the United States, the validation test used most often is the WB (Western Blot).

The achievable false-positive rate of sequentially performed EIA and WB tests can be <0.001% (<1/100,000 persons tested)." (1)

### **References**

(1) Morbidity and Mortality Weekly Report (Vol 36. No. 52, January 8, 1988). pp 833-840

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