**Section 450.730 Western Blot Assay Testing Procedures**

All laboratories which conduct the Western blot assay shall comply with the following requirements.

a) Western blot assay Testing Procedures

1) Western blot assay kits licensed by the United States Food and Drug Administration (FDA) shall be performed on specimens which have been found to be repeatably reactive using the enzyme-linked immunosorbent assay (ELISA) test. The laboratory shall perform a Western blot assay test to determine reactivity with viral polypeptides in accordance with manufacturer's recommendations or package insert.

2) When a Western blot assay kit that is not licensed by the FDA is utilized, the testing procedure must be able to demonstrate and reproduce in a second demonstration at least the viral polypeptides in accordance with recommendations of the Centers for Disease Control, Association of State and Territorial Public Health Laboratory Directors, or American Association of Blood Banks.

3) Western blots must have clear backgrounds and lack non-specific banding; and all banding should be distinct and uniform as well as reproducible.

4) The final blots of non-licensed kits must be examined to determine if the antibodies reacted specifically with HIV polypeptides. Western blot interpretations shall be consistent with the manufacturer's recommendations or package insert.

b) Laboratory Certification and Quality Control

1) The laboratory prior to using any given lot of a non-licensed Western blot kit, shall test all lot material with control sera consisting of negative (no reaction), weakly positive (some reaction – but not strong), and positive (strong, very noticeable reaction) sera. The laboratory shall ensure that the reagent lots are correctly identified with the above control sera. Any and all reagents not meeting the laboratory's specified criteria established in accordance with the quality control system methodologies in Section 450.1150(g) shall not be utilized for testing.

2) The laboratory shall maintain internal viral Western blot quality control for all Western blot assay. All internal Western blot quality control results shall be maintained by the laboratory for review by the Department.

3) The laboratory shall participate in at least one proficiency testing program for ELISA and Western Blot screening and supplemental testing for viral antibodies offered by the College of American Pathologists, the American Association of Bioanalysts, or the Department. A copy of all proficiency testing evaluation reports shall be made available for review by the Department.

(Source: Amended at 13 Ill. Reg. 11573, effective July 1, 1989)