

- 3) Association of Public Health Laboratories. Suggested Reporting Language for the HIV Laboratory Diagnostic Testing Algorithm. January 2019. Available at [APHL Publications](#). Accessed 11/19/2019.

## WESTERN BLOTT ASSAYS

### Inspector Instructions:

 READ	<ul style="list-style-type: none"> <li>Sampling of western blot policies and procedures</li> </ul>
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#### IMM.41500 Molecular Weight Markers

Phase II

**Known molecular weight markers are included and reviewed with each Western blot assay of patient samples.**

**Evidence of Compliance:**

- ✓ Records of QC for known markers

#### IMM.41600 Western Blot Separations

Phase II

**Western blot separations are satisfactory with sufficient resolution (low background, clear signal, absence of bubbles, etc.) to interpret band size easily.**

#### IMM.41700 Acceptable Limits - Controls

Phase II

**Acceptable limits are set for controls of procedures where the Western blot bands are quantified.**

*NOTE: The criterion to designate a Western blot test as positive is based on the detection of a certain combination of positive bands. The laboratory should define a minimum intensity that allows a band to be considered positive.*

**Evidence of Compliance:**

- ✓ Records of defined acceptable limits for control range of each lot

#### IMM.41800 Interpretation

Phase II

**Objective criteria are defined for interpretation of Western blot.**



**REFERENCES**

- 1) Clinical and Laboratory Standards Institute (CLSI). *Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection*. 2nd ed. CLSI guideline M53. Clinical and Laboratory Standards Institute, Wayne, PA; 2023.
- 2) Clinical and Laboratory Standards Institute. *Western Blot Assay for Antibodies to Borrelia burgdorferi; Approved Guideline*. CLSI document M34-A. CLSI, Wayne, PA, 2000.
- 3) Engstrom SM, Shoop E, Johnson RC. Immunoblot interpretation criteria for serodiagnosis of early Lyme disease. *J Clin Microbiol* 1995;33:419-22
- 4) Dressler F, Whelan JA, Reinhart BN, Steere AC. Western blotting in the serodiagnosis of Lyme disease. *J Infect Dis* 1993;167:392-400