

- 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 BLOT ASSAYS

Inspector Instructions:



- Sampling of western blot policies and procedures

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