

# Comparison of a Non-licensed Line-Immunoassay (LIA) and an Approved Western Blot Assay in the Canadian NLHRS HIV-Ab Testing Algorithm Demonstrates the Poorer Specificity Associated with the HIV-1 Western Blot

<i>Abstract Category:</i>	New HIV Diagnostic Technologies
<i>Primary Author:</i>	John Kim
<i>Affiliation:</i>	National Lab for HIV Reference Services, Public Health Agency of Canada, Ottawa, Canada
<i>Co-Authors:</i>	L. Malloch, B. Calder-Kent, Y. Adonsu-Hoyi

## OBJECTIVE

A 5-year review of samples submitted to the NLHRS for HIV serological testing was undertaken to compare a LIA and WB assay in resolving samples initially submitted as indeterminate by provincial labs. This was undertaken to address poorer specificity in the WB on negative samples.

## METHODS

Test results were reviewed from greater than 1000 samples. For this study we narrowed the samples to those in which results were discordant in either the Bio-Rad GS HIV-1 WB or InnoGenetics INNO-LIA HIV-1/2 Score and in which a final diagnosis of negative for anti-HIV Ab was diagnosed. This final diagnosis was based on the NLHRS algorithm which utilizes 3 supplementary assays including the LIA, WB and radioimmunoprecipitation (RIPA) and PCR when available.

## RESULTS

Of samples in which the final diagnosis was negative for anti-HIV Ab, 232 were WB-ind/LIA-neg vs 15 that were WB-neg/LIA-ind. Of the 232 WB-ind/LIA-neg samples cross reactivity on the western blot was observed as [class-indiv antigen]; gag-207; p24(117), p55(66), p17(24); pol-86; p51(30), p31(29), p66(27) and env-20; gp160(15), gp41(4), gp120(1). Of the 15 WB-neg/LIA-ind samples, cross reactivity on the line -immunoassay was observed in gp120(3), gp41(3), p24(5) and p17(2). Non-specific reactivity in the WB was mostly observed for the gag (207) and pol (86) classes with the individual antigens p24 117) and p55 (66) demonstrating the highest degree of cross reactivity. Interestingly, non-specific reactivity for the 15 WB-neg/LIA-ind samples were almost equally divided between the structural gp120/gp41-(6) and non-structural proteins p24/p17(7).

## CONCLUSIONS

Canadian labs are restricted to using kits that have been approved by regulatory bodies which at the time is limited to only the HIV-1 western blot. Unfortunately this can often lead to unresolved final diagnoses on patient samples, especially on those that ultimately will be negative. The LIA, while unlicensed, is made available to us as a national reference lab and has clear benefits in helping to resolve final HIV status. Furthermore the test can also serve as an aid in HIV-2 diagnosis. Efforts are underway in Canada to obtain this kit for general use.