Comparative Evaluation of Five Lassa Virus IgG Immunoassays for Seroprevalence Studies and Vaccine Trial Support in West Africa

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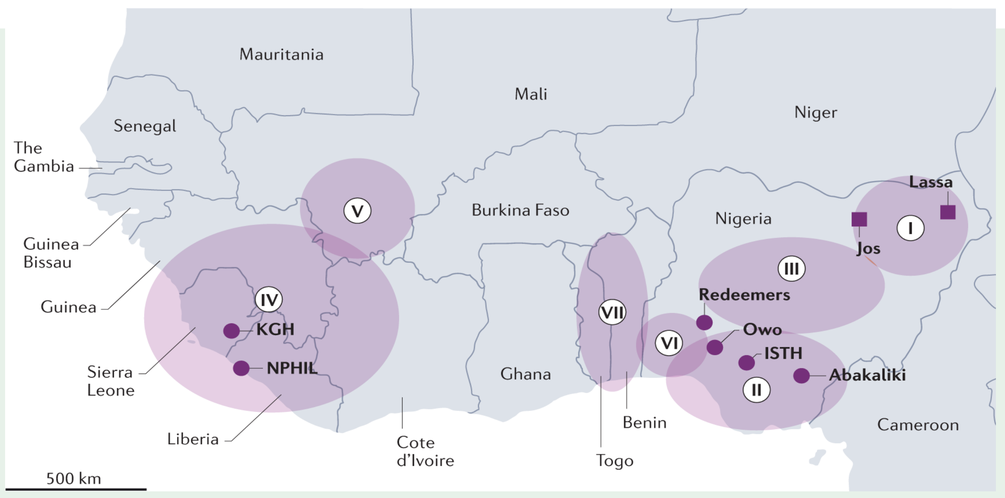
Background

- Serological testing is pivotal in diagnosing Lassa fever and conducting sero-epidemiological studies essential for planning vaccine efficacy trials.
- For reliable use, assays should demonstrate high sensitivity (>90%) and specificity (>90%).
- Performance data on available Lassa virus (LASV) IgG assays are limited.
- To support clinical trials in West Africa, we conducted a comparative evaluation of five LASV-specific IgG immunoassays to determine their diagnostic utility.

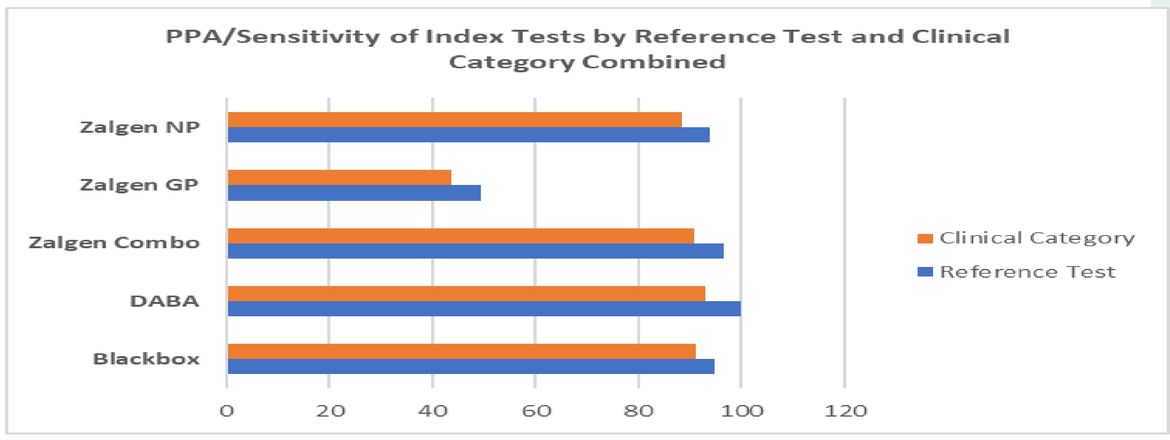


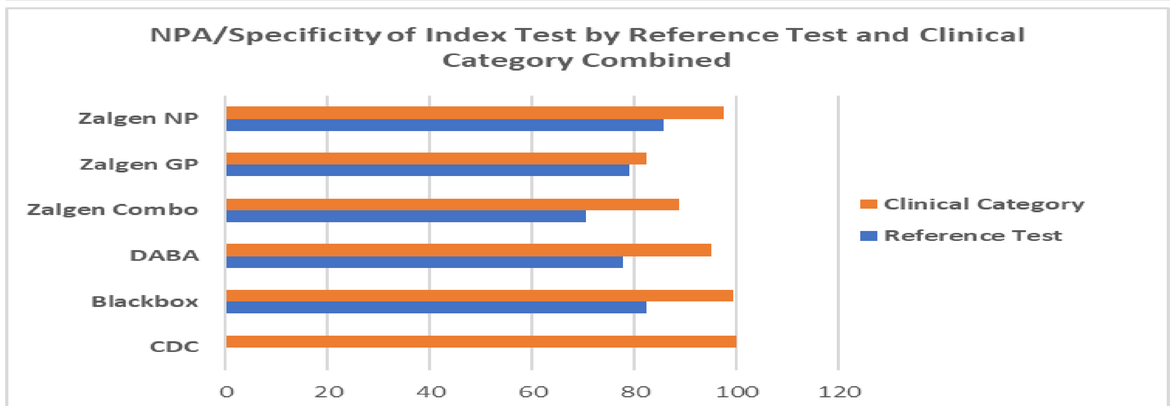
Methods

- Study locations were Irrua Specialist Teaching Hospital, Nigeria and Kenema General Hospital, Sierra Leone
- A total of 148 archived LASV-RT-PCR-positive sera from Nigeria and 158 LASV –antigen-positive sera from Sierra Leone were tested. LASV-naïve sera from Gabon served as negative controls
- The U.S CDC LASV IgG assay was used as the reference test. Positive percent agreement (PPA) and negative percent agreement (NPA) were calculated against either the reference assay or clinical classification based on historical data and sample origin.
- Performance metrics were computed for LASV –exposed and LASV –naïve samples.

Results

- Based on combined analysis, PPA ≥ 90% was observed in 3/5 assays based on comparison to the reference test, (DABA IgG, BLACKBOX IgG, and Zalgen NP IgG).
- PPA based on comparison to the clinical category showed similar trends.
- NPA ≥ 95% was not observed for any of the index tests compared to the reference test.
- NPA ≥ 95% was observed for 3/5 index assays compared to the clinical category (DABA IgG, BLACKBOX IgG, Zalgen NP IgG), with the CDC IgG assay demonstrating 100% NPA.





Conclusions and Recommendations

Based on our analysis, three IgG assays (Blackbox IgG, Zalgen NP IgG, DABA IgG) would be appropriate for use to assess seroprevalence of LASV specific IgG in Sierra Leone and Nigeria, and also to support the evaluation of immune response to Lassa fever vaccines in West Africa.

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