Evaluation of Four Lassa Virus IgM Immunoassays for Early Detection and Seroprevalence Studies in West Africa

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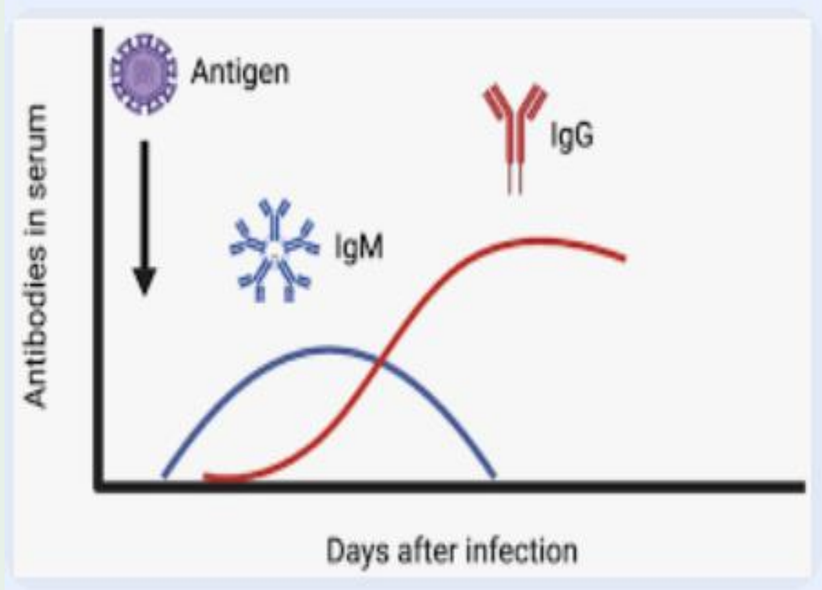
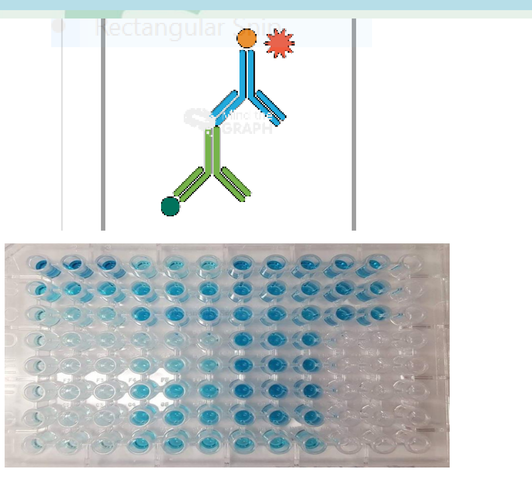
Background

- Immunoglobulin M (IgM) antibodies are the earliest serologic markers of acute Lassa virus (LASV) infection
- LASV –specific IgM assays essential for early diagnosis and to assess immune responses to natural infection or vaccination.
- For reliable use, IgM assays should demonstrate high sensitivity (>90%) and specificity (>90%).
- Performance data on available LASV IgM assays are limited
- We evaluated the diagnostic performance of four commercial LASV IgM assays to determine their applicability in seroprevalence assessments and vaccine trials within Lassa-endemic regions



Methods

- A retrospective study conducted at Irrua Specialist Teaching Hospital (Nigeria), Kenema Government Hospital (Sierra Leone), and Phebe Hospital (Liberia)
- Four LASV-specific IgM assays were assessed using archived frozen sera from RT-PCR-confirmed acute Lassa fever cases in Nigeria and Liberia, and LASV antigen-positive cases from Sierra Leone.
- LASV-negative sera were obtained from Gabon (non-endemic), and the U.S. CDC LASV IgM ELISA was used as the reference standard
- Sample size for combined analysis was 150 positive samples and 150 negative samples - Each site used a test panel composed of approximately 50 IgM positive endemic samples, and 50 IgM negative samples from a non-endemic country (Gabon)



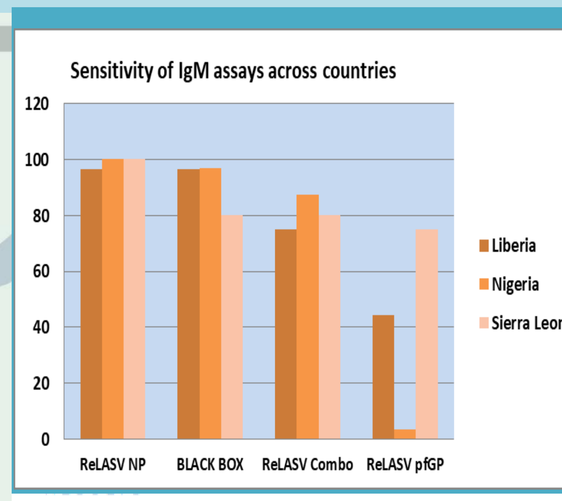
Results

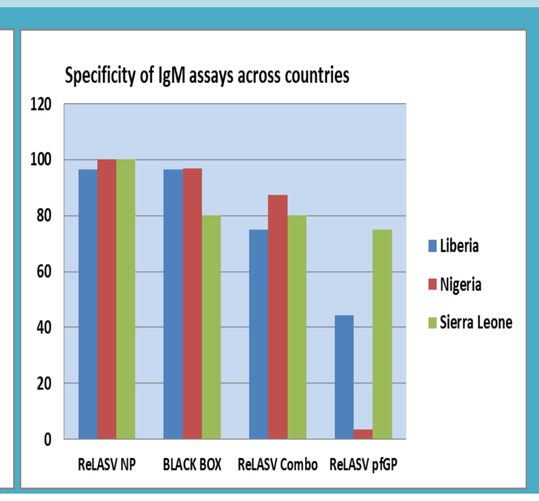
LIBERIA
2/4 assays showed a sensitivity >90%, the Zalgen ReLASV Combo NP pfGP IgM elisa (96.4%) and the ReLASV NP IgM ELISA (96.4%). No assay displayed a test specificity >95%, but BLACKBOX IgM ELISA was highest 90.00%).

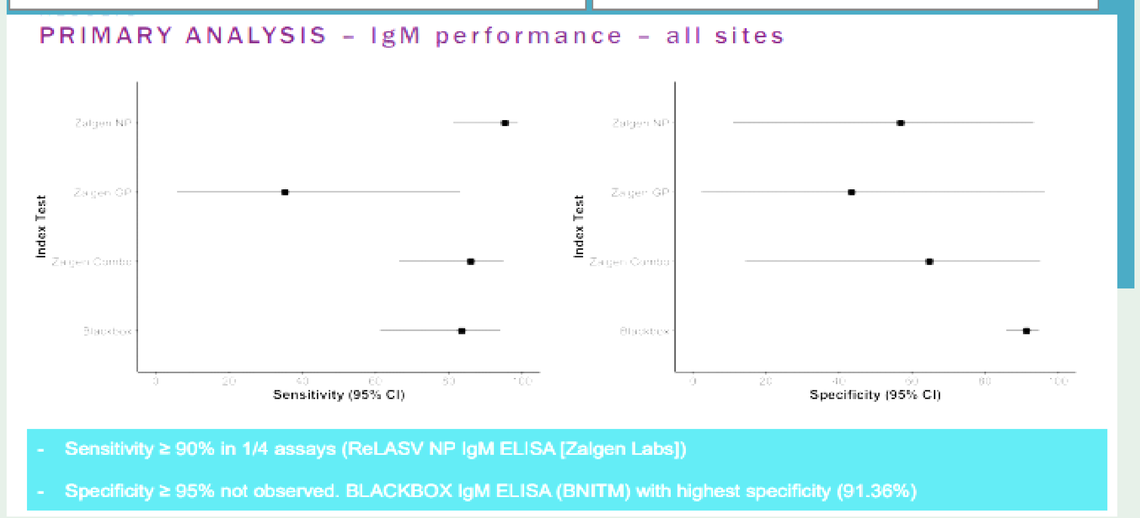
NIGERIA
2/4 assays showed a sensitivity of 90%: the Zalgen ReLASV NP IgM ELISA (100.0%) and the BLACKBOX IgM ELISA (96.7%) (95%CI: 83.3 -94.4). The highest test specificity was the BLACKBOX IgM ELISA (92.2%)

SIERRA LEONE
1/4 assay, the Zalgen ReLASV NP IgM ELISA, showed a test sensitivity of >90% (100.0%) and only ¼ assay, the BLACKBOX IgM ELISA, showed a test specificity >95% (100.0%)

COMBINED
- One assay has a test sensitivity >90%: the Zalgen ReLASV NP IgM ELISA (95.3%)
- The Zalgen pfGP had the lowest sensitivity (35.3%)
- No assay showed a test specificity >95%. The highest specificity in the BLACKBOX IgM ELISA (91.4%)







Conclusions and Recommendations

Although none of the tests meet the recommendation performance characteristics, in high LASV prevalence settings, the BLACKBOX IgM ELISA, Zalgen Relasv Combo NP – pfGP IgM ELISA, and the ReLASV NP IgM ELISA, would be suitable for assessing seroprevalence of LASV-specific IgM in the 3 sites

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