Advancing HIV Diagnostics: Evaluating the Emerging Multisure HIV1/2 Rapid Confirmatory Test as an Alternative to the Traditional Gold Standard Assays

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Abstract

Background: HIV remains a significant global health challenge, demanding routine testing for early detection. CLIA screening assay, particularly Architect HIV, followed by immunoblot confirmation assay such as INNO-LIA, is the standard procedure. However, due to indeterminate results and limitations of immunoblot assays, the CDC recommended utilizing Geenius HIV1/2 assay for confirmatory testing. This study compares two advanced HIV1/2 rapid tests as efficient alternatives for HIV confirmation. **Method:** 224 Architect HIV positive and HIV negative samples were utilized. These included true positives (n=38; Architect positive & INNO-LIA positive), true negatives (n=139; Architect negative & INNO-LIA negative), false positives (n=20; Architect positive & INNO-LIA negative) and INNO-LIA indeterminate (n=27). Samples were screened with Architect HIV and confirmed by INNO-LIA and PCR. All samples were re-tested by Multisure HIV1/2 and Geenius HIV1/2. Assessment performed via performance evaluation metrics. **Results:** Both rapid tests showed 100% sensitivity and specificity compared to INNO-LIA. For IND cases, Multisure HIV1/2 classified 81.5% as negative, while Geenius HIV1/2 classified 55.6%. Multisure had higher specificity (89.2%) and PPV (89.5%) than Geenius (82.9% and 84.6%) when compared to PCR. **Conclusion:** Multisure HIV1/2 is a reliable potential addition to the CDC algorithm as an alternative to immunoblot assays.

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