U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Laboratory-based HIV-1/2 Ag/Ab Immunoassay Performance in the United States, 2019-2023

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BACKGROUND

The Centers for Disease Control and Prevention (CDC) recommends routine HIV screening of persons aged 13-64 years and additional testing for those with exposure risk or symptoms. All positive HIV antigen/antibody (Ag/Ab) immunoassay results should be confirmed with HIV antibody differentiation and, in the case of conflicting results, an HIV RNA test. We evaluated the performance of HIV Ag/Ab testing using data from a major commercial lab in the United States.

METHODS

We analyzed HIV testing data from individuals ≥ 13 years tested by Quest Diagnostics between 2019 to 2023 with complete CDC-recommended algorithm testing for a positive Ag/Ab test. We calculated the testing volume and the positive predictive values (PPV) by age group and sex. PPV were calculated as the proportion of HIV Ag/Ab tests with a positive result confirmed by the CDC recommended HIV algorithm among all Ag/Ab tests with an initial positive result.

RESULTS

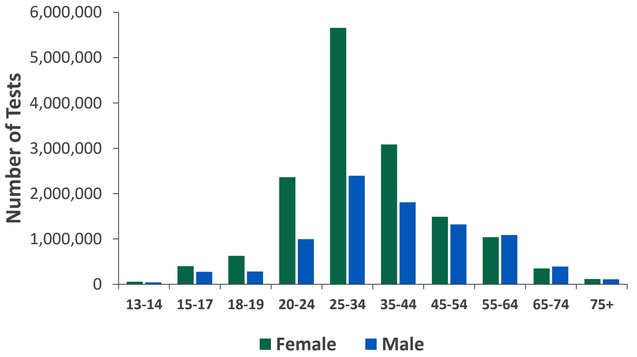
We identified a total of 23,944,766 HIV Ag/Ab tests. Of these, 36.5% were performed on men and 63.5% on women, with the majority (80.0%) among individuals aged 20-54 years. Overall, the PPV of the HIV Ag/Ab test was 78.6%. The PPV was higher in men (87.5%) than in women (58.4%). For men, PPV was lowest among those aged 13−14 years (27.8%) and peaked at 89.2% for those aged 25−34 years. PPV was > 80% for men aged 20−74 years and 70.6% for men 75+. PPV was 49.7% for women of reproductive age (15-44) and increased to 74.2% for women aged 55−64 years. Except for persons aged 13−14 years, PPV was consistently lower for women compared with men.

CONCLUSIONS

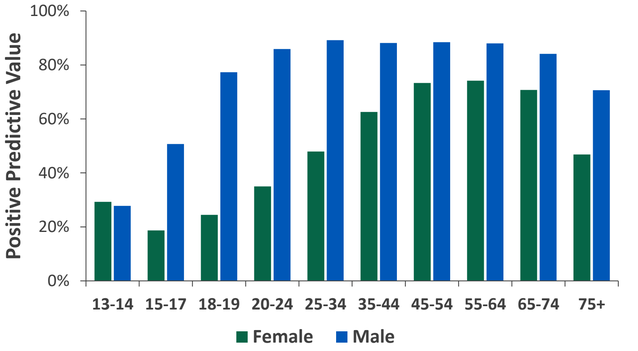
This analysis found relatively higher PPV among groups most likely to be tested by providers based on clinical or risk-based needs: men, persons reporting HIV exposure risk, persons initiating or continuing PrEP, and symptomatic individuals. Lower PPVs were observed among women of reproductive age, likely due to near-universal screening among pregnant women who have a low overall prevalence of HIV. The reported PPV of the Ag/Ab test highlights the need to conduct the entire recommended HIV diagnostic algorithm to confirm an HIV diagnosis. Understanding the performance of HIV Ag/Ab test results for specific populations may also facilitate test interpretation and recommendations for future HIV testing.

HIV antigen/antibody testing generally shows high positive predictive value (PPV) in men but lower PPV in women and younger and older age groups, highlighting the importance of complete diagnostic confirmation in all populations.

A. Number of HIV Ag/Ab Tests by Age Group and Sex, 2019-2023



B. Positive Predictive Value of HIV Ag/Ab Tests by Age Group and Sex, 2019-2023



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 The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.