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Abstract (poster session)

Comparative evaluation of electrochemiluminescence immunoassay and ELISA for HIV screening in a multi-ethnic region of China

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Objective: Although automated chemiluminescence immunoassay (CLIAs) are gradually replacing the enzyme immunoassays (EIA), there are limited published studies on the comparative evaluation of these two different assays. We compare the performance of fourth-generation electrochemiluminescence immunoassay (ECLIA) and third-generation enzyme linked immunosorbent assay (ELISA) for human immunodeficiency virus (HIV) screening and gauge whether the shift from ELISA to ECLIA or alternative algorithms could be better in a multiethnic region of China. Methods: We identified a large number of specimens (345,492) tested under routine conditions of a hospital laboratory using two different assays from Jan 2008 to Aug 2011 in urban centers with high sample throughput. Until Oct 2010, screening for HIV infection was carried out with a third generation ELISA. Since Nov 2010, a fourth-generation immunoassay ECLIA has been used at our laboratory for both diagnosis and screening purposes. Specimens with initially repeatedly reactive and western blot negative or indeterminate results were considered false-positive. Among all initially repeatedly reactive specimens, we evaluated the proportion of false-positive, positive predictive value (PPV), and western blots results in relation to ratios. Results: The reproducibility of assays was determined by intra-class correlation coefficient (ICC). Precision results for assays are 0.994(ELISA)and 0.998 (ECLIA). HIV prevalence was 0.23% using ELISA and 0.26% using ECLIA. The false-positive rate was lower for ELISA than ECLIA (0.03% vs. 0.11%, odds ratio 0.28 [95% confidence interval 0.21, 0.37]). The PPV for ELISA (87.9%) was significantly higher than that for ECLIA (69.4%). Conclusions: The performance of both assays was satisfactory in this setting. Increased specificity without compromising sensitivity can be achieved by slightly increasing COI ratio in ECLIA. Caution is needed in changing a test or combination of tests. Performance is important, but not sufficient. Since none of these tests are perfect, different testing algorithms should be developed for different clinical settings, taking into account the local conditions.