Comparative assessment of SARS-CoV-2 serology in healthcare workers with Abbott Architect, Roche Elecsys and The Binding site ELISA immunoassays.

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## Abstract

Background: SARS-CoV-2 serology testing is key for assessing seroprevalence and community transmission in both symptomatic and asymptomatic contexts. Robust assay development requires assessment in asymptomatic and non-hospitalised individuals to determine if serological assays are sensitive to detect mild antibody-responses. Our study evaluated the performance characteristics between two high-throughput SARS-CoV-2 IgG nucleocapsid assays (Abbott and Roche) and The binding site (TBS) Anti-Spike IgG/A/M ELISA kit in healthcare workers. Methods: 252 samples were collected from Portsmouth Hospital University NHS Trust (PHU) and The Dudley Group NHS Trust and analysed for SARS-CoV-2 serology. We derived concordance, agreement and assay performance as well as using receiver operating characteristic (ROC) curves to redefine the assay threshold of the Abbott assay Results: Result concordance between the Abbott and TBS was 66%. Discrepant samples were analysed using the Roche assay which showed 100% agreement with the TBS assay. In samples analysed >58 days post-PCR, the sensitivity of Abbott and Roche was 100%. In samples analysed >100 days post-PCR the sensitivity of the Abbott assay dropped to 77.2% but remained at 100% for the Roche assay. A redefined Abbott threshold of 0.64 increased the sensitivity to 90% giving results similar to the Roche and TBS assays. Conclusion: This study demonstrated use of manufacturer cut-off threshold for Abbott SARS-CoV-2 IgG immunoassay induced lower sensitivity and higher false negative outcomes in comparison to TBS and Roche. Our findings established TBS can be implemented as a viable alternative for SARS-CoV-2 serology testing where high-throughput assays are not available on site.

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