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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

Statement of Problem: SARS-CoV-2 serology testing is key for assessing seroprevalence and antibody response post-vaccination in immunocompromised patients. Consequently, several immunoassays have been designed to meet global laboratory infrastructures. However, immunoassay performance has been primarily elucidated through severe COVID-19 patient-samples, whereby, combination of high viral-load and robust immune-responses could overestimate assay sensitivities. Therefore, accurate detection of both asymptomatic and non-hospitalised individuals is pivotal for SARS-CoV-2 serological assay development. We therefore evaluated the Abbott, Roche and TBS immunoassays in non-hospitalised healthcare workers to identify both assay sensitivities and redefine assay thresholds required for optimisation.

Methodology: 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.

Findings: 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 Abbott assay had a lower sensitivity 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. Furthermore, anti-spike assays, such as TBS, could be used to monitor vaccination responses to deduce SARS-CoV-2 population-immunity. Further optimisation studies are required to evaluate the performance characteristics of these assays which could facilitate widescale sero-epidemiological surveillance.

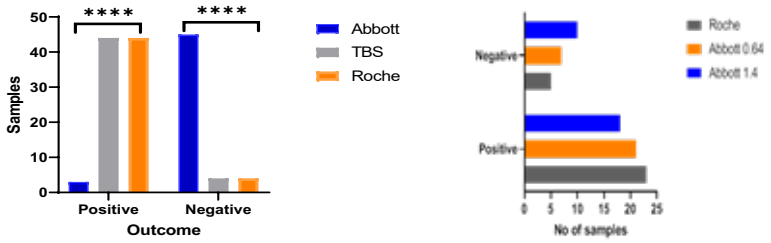

Fig 1. Left Panel: SARS-CoV-2 serological outcomes derived from a three-way method comparison. Right panel: Serological outcomes using a re-defined cut-off threshold (0.64) between Abbot-Architect versus Roche

Biography

Dr Alison Whitelegg is a Consultant Clinical Scientist in Immunology at University Hospital Southampton and Immunology Clinical Lead at Portsmouth Hospitals NHS Trust where she has responsibility for a wide repertoire of laboratory assays. She has expertise in clinical flow cytometry, functional lymphocyte and neutrophil assays and a research background in T cell immune responses and vaccine specific immune responses as an assessment of immunocompetence in immunodeficiency and transplant patients. Her Immunology career began at the Anthony Nolan Research Institute and she has spent a further 20 years in the NHS. Alison is educational tutor for Immunology Clinical Scientists in the UK and active member of the Immunology Professional Committee branch of Association of Clinical Biochemistry and Laboratory Medicine.

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