SARS-CoV-2 Point of Care Antibody Testing - an emerging diagnostic to inform therapeutic and vaccine intervention

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Introduction

Background
As the COVID-19 pandemic progresses, identifying which populations will benefit from public health preventative and therapeutic interventions is becoming increasingly important. Determining SARS-CoV-2 antibody serostatus has multiple roles including assessment of community prevalence of infection, assessment of response to vaccination and in clinical decision making related to emerging COVID-19 therapeutics. Standard laboratory assays are not universally accessible, are time-intensive and in low-resource populations may be cost-prohibitive. We investigated the use of a lateral flow point of care test (POCT) for SARS-CoV-2 spike antibodies in comparison to a standard laboratory assay as part of the PRECISE Study, a cross sectional seroprevalence study of SARS-CoV-2 antibodies in Irish healthcare workers (HCW).

The PRECISE Study
The PRECISE Study (Prevalence of COVID-19 in Irish Healthcare Workers) is a multi-leg, cross sectional seroprevalence study of SARS-CoV-2 antibodies in Irish HCW across two hospital sites.

The fourth leg of this study, PRECISE 4, was undertaken in November 2021, immediately prior to the roll-out of booster COVID-19 vaccination doses for HCWs to assess the durability of antibody responses and changing epidemiology of COVID-19 in HCWs in the era of booster vaccinations

As part of the PRECISE 4 study we tested a subset of participant samples for COVID-19 antibodies using both the laboratory-based Roche assay and using the POCT.

Methods

Serology samples were analysed using the Roche Elecsys-S Anti-SARS-CoV-2 assay for the qualitative and quantitative detection of total (IgG/A/M) anti-spike(S) antibodies. The Healgen SARS-CoV-2 Antibody Rapid Test Cassette, a lateral flow POCT was used to determine the qualitative presence of anti-S antibodies.

Pre-pandemic serology samples were also tested via the POCT to serve as negative controls. Participant samples were analysed on both platforms to assess sensitivity and specificity of the POCT.

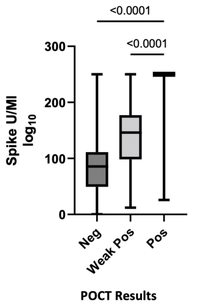
PRECISE Study
Antibody Test for COVID-19

Results

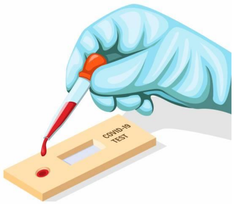
- 1512 samples were analysed using the Healgen SARS-CoV-2 Antibody Rapid Test Cassettes and the Roche elecsys Spike immunoassay for the detection of antibodies to SARS-CoV-2 (Results in Table 1).
- Sensitivity of the POCT was 97.5% and specificity 100%
- All 50 pre-pandemic negative control sera returned negative anti-S results via POCT.
- Analysis of variance (ANOVA) was used to compare the differences between the means of the negative, weak positive and positive results groups (Graph 1).

Result	Healgen Point of Care Antibody Test N(%)	Roche ELECSYS-S Anti-SARS-CoV-2 Spike Antibody Positive N(%)	Roche ELECSYS-S Anti-SARS-CoV-2 Spike Antibody Negative N(%)
Positive Result	1412 (93.39%)	1475 (99.8%)	0
Weak Positive Result	63 (4.16%)		
Negative Result	37 (2.4%)	34 (2.2%)	3 (0.2%)
Total	1512	1509	3

Table 1. Comparison of Healgen Point of Care Antibody Test Results with Roche ELECSYS Anti SARS- CoV-2 Spike Antibody Test Results



Graph 1. Comparison of POCT results (negative, weak positive, positive) with absolute anti-spike titre level using Roche assay.

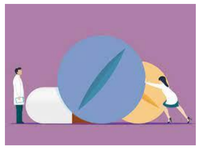


Conclusion/Discussion

- We demonstrate robust sensitivity and specificity of the Healgen POCT for the qualitative identification of anti-S antibodies with a high level of correlation with a standard laboratory assay. There is a statistically significant difference between negative and positive result findings on POCT.
- This data suggests point of care antibody testing may be used to help to identify high risk populations and thus protect them through additional vaccinations and access to anti-viral medications. Point of care tests are cost effective, rapid, and easy to use. They are likely to become an important part of our disease management and control strategy through the possible future waves of this COVID-19 pandemic.

POCT are cheap and easy to use. They are in use for example in malaria, sickle cell disease and HIV diagnosis in many low resource setting [4-6]. COVID-19 antibody testing using POCT may give access to HCWs in settings without formal lab testing.

Viral antibody testing in other diseases for example hepatitis B and varicella zoster helps inform the need for further vaccines and evaluate national vaccination programmes



The choice of who to treat with expensive, novel anti viral therapies may be aided by antibody testing.