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Development of an in-house COVID-19 serology ELISA Test

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ABSTRACT

Background: COVID-19 pandemic created an unprecedented demand for reagents and diagnostic tools to confirm COVID-19 cases. Thus, the development of a robust in-house diagnostic test is considered of high importance. Within a few days after exposure, the human body produces specific antibodies that recognize the surface proteins of the invading SARS-CoV-2 virus[1]. Therefore, virus specific immunoglobulins are neutralizing antibodies and their appearance in the blood is a good sign of immunity[2]. The aim of this study was to develop an in-house COVID-19 serology ELISA test to quantify induced antibody responses. This test can help identify convalescent plasma donors with high antibody titers that can be used to treat other patients.

Methods: Spike protein antigen is highly expressed in SARS-CoV-2[3]. Recombinant protein corresponding to the spike receptor-binding domain (RBD), which binds to specific antibodies circulating in COVID-19 patients' blood was used as the antigen in this colorimetric ELISA test. Briefly, a 96-microtiter well plate was coated with RBD protein, where serum dilutions were added. Antibody titers were detected using an anti-human IgG- peroxidase labelled antibody and the substrate o-phenylenediamine dihydrochloride; measured at optical density (OD) of 450 nm (Figure 1).

Results: The in-house quantitative serology test was validated using serum samples collected from severe COVID-19 patients (n = 282) admitted to the intensive care unit at Hamad General Hospital. Serum samples from non-COVID-19 (n = 10) were used as a negative control. We detected high antibody titers in ~90% of COVID-19 sera. In contrast, no SARS-CoV-2 specific antibodies were detected in the serum of non-infected subjects (n = 6), pooled human serum collected before 2019, or Middle East Respiratory Syndrome (MERS) infected subjects (n = 3) confirming the specificity and the sensitivity of this in-house serology test.

Conclusion: This in-house quantitative serology test is sensitive, specific, and inexpensive. The test can address the rising issue of COVID-19 supply chain globally and foster the capacity-building efforts envisioned by Qatar University.

Keywords: COVID-19, SARS-CoV2, serology, antibody titer, ELISA

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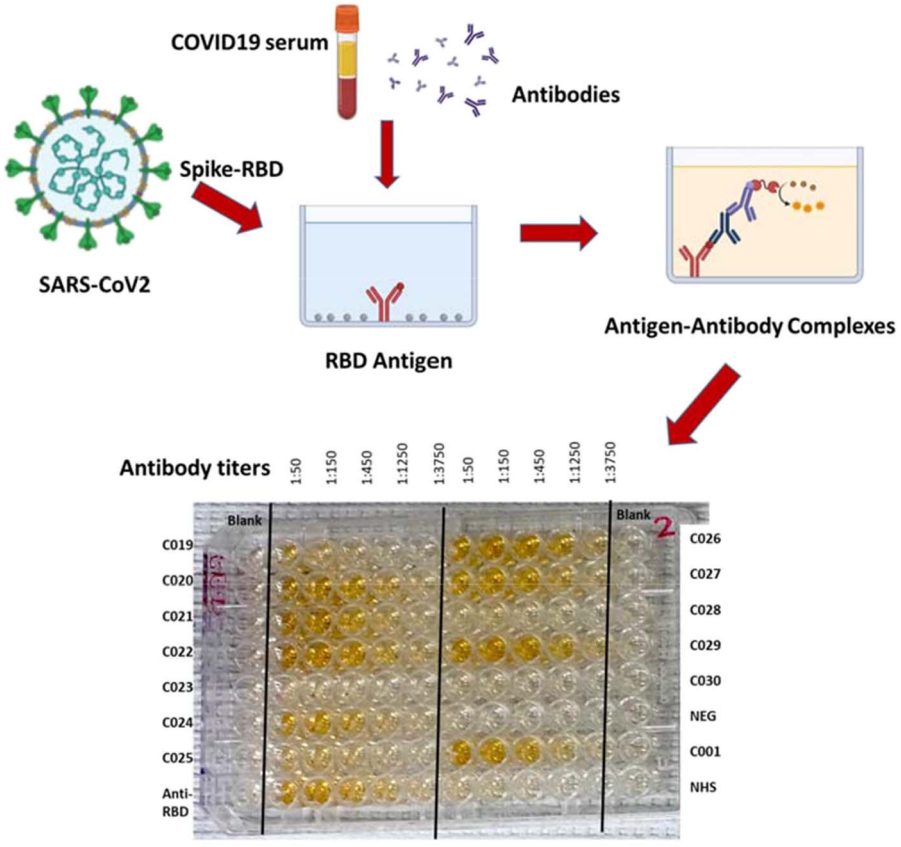

Figure 1. Schematic representation of the in-house serology quantitative ELISA test.

Ethical approval statement: The study was reviewed and approved by Medical Research Center and IRB committee at Hamad Medical Corporation (MRC-01-20-1065). Collected serum samples were processed in certified BSL3 facility where sera were heat-inactivated to mitigate potential hazard and render it suitable for BSL2 further processing.

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