

عنوان مقاله:

Application and Validation of SARS-CoV-2 RBD Neutralizing ELISA Assay

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خلاصه مقاله:

The establishment of an approach for detecting the anti-severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2)-receptor-binding domain (RBD) neutralizing antibodies (nAbs) by a safe, easy, and rapid technique without requiring the use of live viruses is essential for facing the coronavirus disease 2019 (COVID-19) pandemic. Depending on competitive enzyme-linked immunosorbent assay (ELISA) methodology, the current study assay was designed to simulate the virus-host interaction using purified SARS-COV-2-RBD from the spike protein and the host cell receptor human angiotensin-converting enzyme 2 protein. The performance of this in-house neutralizing ELISA assay was validated using freshly prepared standards with different known concentrations of the assay. In this regard, a cohort of 50 serum samples from convalescent COVID-19 individuals with different disease severity at different time points post-recovery and a cohort of 50 serum samples from healthy individuals were processed by the in-house developed assay for detecting SARS-CoV-2 nAbs, in comparison with a commercial total anti-SARS-CoV-2 IgG antibody assay as a gold standard. The assay obtained a sensitivity of 88% (95% CI: 75.69-95.47) and a specificity of 92% (95% CI: 80.77- 97.78%). A negative strong correlation was demonstrated in the standard curve between the optical density absorbance and log concentration of the nAbs with a statistical measure of r^2 (coefficient of determination) = 0.9539. The SARS-COV-2-RBD neutralizing ELISA assay serves as a high throughput qualitative and quantitative tool that can be applied in most laboratory settings without special biosafety requirements to detect anti-RBD nAbs for seroprevalence, pre-clinical, and clinical evaluation of COVID-19 vaccines efficiency and the rapid selection of convalescent plasma donors for the treatment of COVID-19 patients.

کلمات کلیدی:

covid-19, nAbs, neutralizing antibodies, SARS-COV-2-RBD neutralizing ELISA assay

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