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Enhancing the Sensitivity of Antigen Based Sandwich ELISA for COVID-19 Diagnosis in Saliva Using Gold Conjugated Nanobodies

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Abstract : Development of sensitive non-invasive tests for detection of SARS-CoV-2 antigens is imperative to manage the extent of infection throughout the population, yet, it is still challenging. Here, we designed and optimized a sandwich enzyme-linked immunosorbent assay (ELISA) for SARS-CoV-2 S1 antigen detection in saliva. Both saliva samples and nasopharyngeal swapswere collected from 170 PCR-confirmed positive and negative cases. Gold nanoparticles (AuNPs) were conjugated with S1protein receptor binding domain (RBD) nanobodies. Recombinant S1 monoclonal antibodies (S1mAb) as primery antibody and gold conjugated nanobodies as secondary antibody were employed in sandwich ELISA. Our developed system were optimized to achieve 87.5 % sensitivity and 100% specificity for saliva samples compared to 89 % and 100% for nasopharyngeal swaps, respectively. This means that saliva could be a suitable replacement for nasopharyngeal swaps No cross reaction was detected with other corona virus antigens. These results revealed that our developed ELISAcould be establishedas a new, reliable, sensitive, and non-invasive test for diagnosis of SARS-CoV-2 infection, using the easily collected saliva samples.

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