Novel Point of Care Test for Rapid Diagnosis of COVID-19 Using Recombinant Nanobodies against SARS-CoV-2 Spike1 (S1) Protein

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Abstract : In the recent COVID 19 pandemic, experts of public health have emphasized testing, tracking infected people, and tracing their contacts as an effective strategy to reduce the spread of the virus. Development of rapid and sensitive diagnostic assays to replace reverse transcription polymerase chain reaction (RT-PCR) is mandatory. Our innovative test strip relying on the application of nanoparticles conjugated to recombinant nanobodies for SARS-COV-2 spike protein (S1) & angiotensin-converting enzyme 2 (that is responsible for the virus entry into host cells) for rapid detection of SARS-COV-2 spike protein (S1) in saliva or sputum specimens. Comparative tests with RT-PCR will be held to estimate the significant effect of using COVID 19 nanobodies for the first time in the development of lateral flow test strip. The SARS-CoV-2 S1 (3 ng of recombinant proteins) was detected by our developed LFIA in saliva specimen of COVID-19 Patients No cross-reaction was detected with Middle East respiratory syndrome coronavirus (MERS-CoV) or SARS- CoV antigens. Our developed system revealed 96 % sensitivity and 100% specificity for saliva samples compared to 89 % and 100% sensitivity and specificity for nasopharyngeal swabs. providing a reliable alternative for the painful and uncomfortable nasopharyngeal swab process and the complexes, time consuming PCR test. An increase in testing compliances to be expected.

Keywords: COVID 19, diagnosis, LFIA, nanobodies, ACE2

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