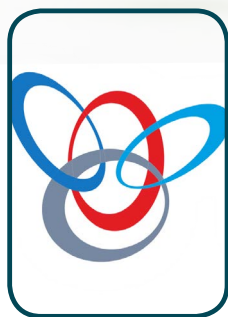


Virology, Infectious Diseases and COVID-19

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Nadin

Validation of a novel fluorescent lateral flow assay for rapid qualitative and quantitative assessment of total anti-SARS-CoV-2 S-RBD binding antibody units (BAU) from plasma or fingerstick whole-blood of COVID-19 vaccinees

Background: Limited commercial LFA assays are available to provide a reliable quantitative measurement of the total binding antibody units (BAU/mL) against the receptor-binding domain of the SARS-CoV-2 spike protein (S-RBD). Aim: To evaluate the performance of FinecareTM2019-nCoV S-RBD LFA and its fluorescent reader (FinecareTM-FIA Meter) against the following reference methods (i) The FDA-approved Genscript surrogate virus-neutralizing assay (sVNT), and (ii) three highly performing automated immunoassays: BioMérieux VIDAS®3, Ortho VITROS®, and Mindray CL-900i®. Methods: Plasma from 488 vaccinees were tested by all aforementioned assays. Fingerstick whole-blood samples from 156 vaccinees were also tested by FinecareTM. Results and conclusions FinecareTM showed 100% specificity as none of the pre-pandemic samples tested positive. Equivalent FinecareTM results were observed among the samples taken from fingerstick or plasma (Pearson correlation $r=0.9$, $p<0.0001$), suggesting that fingerstick samples are sufficient to quantitate the S-RBD BAU/mL. A moderate correlation was observed between FinecareTM and sVNT ($r=0.5$, $p<0.0001$), indicating that FinecareTM can be used for rapid prediction of the neutralization antibody post-vaccination. FinecareTM BAU results showed strong correlation with VIDAS®3 ($r=0.6$, $p<0.0001$), and moderate correlation with VITROS® ($r=0.5$, $p<0.0001$), and CL-900i® ($r=0.4$, $p<0.0001$), suggesting that FinecareTM be used as a surrogate for the advanced automated assays to measure S-RBD BAU/mL.