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Abstract

The Clinical Potential of Point-of-Care Quantitative Spectrochip Coupled with Lateral Flow Immunoassay during the COVID-19 Pandemic †

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Abstract: Coronavirus disease (COVID-19) is a large-scale global public health challenge that still persists. A method that achieves the rapid quantitative detection of antibodies to assess the body's immune response from a natural COVID-19 illness or the vaccines' effects is urgently needed. In the present study, we integrated a newly designed spectrometer with COVID-19 test strip procedures; this augmentation provides the capacity for a lateral flow immunoassay (LFIA) to be quantitative. Optical interpretation of results by quantitative α index was undertaken, rather than visual qualification. It can be performed quickly in 5–10 min. We compared the developed product with several other serological IgM/IgG antibody reagents on the market by recruiting 111 participants with a suspected COVID-19 infection from March to May 2020 in a single hospital. Taking RT-PCR as the diagnostic gold standard, the quantitative spectral LIFA platform could detect all 12 COVID-19 patients correctly (100% sensitivity, 12/12). In contrast, the sensitivity for ACE Biolab alone is 91.67% (11/12), and for Biomedomics, it is 58.33% (7/12). Methods that use Nucleocapsid (N) + Spike (S) solid-phase antigen (i.e., ACE Biolab, TBG, and Spectrochip +ACE Biolab) perform better compared with those that use Nucleocapsid (Biomedomics) or Spike (ASK) alone. Concerning negative RT-PCR patients, all three antibody testing methods found positive cases. The optical-based platform exhibited the ability of the early detection of immunoglobulins of negative RT-PCR patients. There was an apparent trend of an elevation of IgM levels in the acute phase of infection, then the IgG levels rose again later. It exhibited the risk of a false-negative diagnosis of RT-PCR in COVID-19 testing. The significant detection ability of this new optical-based platform demonstrated clinical potential.

Keywords: COVID-19; lateral flow immunoassay; RT-PCR; serological test; quantitative immunoassay

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Data Availability Statement: All relevant data are within the manuscript and its Supporting information files.

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