

The clinical potential of point-of-care quantitative SpectroChip coupled with lateral flow immunoassay in COVID-19 pandemic

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Abstract: Coronavirus disease (COVID-19) is the current grand global public health challenge. To assess the body's immune response from natural COVID-19 disease or from the effects of vaccines, it is necessary to have a method that meets the rapid quantitative detection of antibodies. We integrated a newly designed spectrochip to our COVID-19 test strip procedures to provide sensitive, quantitative capacity to a lateral flow immunoassay (LFIA). Optical interpretation of results by quantitative α index was taken, rather than visual qualification. This detection method can quickly produce results in 6 minutes. We compared the developed product with several other serological IgM/IgG antibody reagents on the market by recruiting 111 participants of suspected COVID-19 infection from March to May 2020 in a single hospital. Taking RT-PCR positive individuals as the gold standard, the analytical platform (Spectrochip +ACE Biolab) can correctly detect all 12 COVID-19 patients (100% sensitivity, 12/12). In contrast, the sensitivity for ACE Biolab alone is 91.67% (11/12), for Biomedomics 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. This new platform's extraordinary detection ability demonstrated clinical potential.

Keywords: COVID-19; Lateral flow immunoassay; RT-PCR; Serological test; Quantitative immunoassay

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