

N-Terminus Truncated Recombinant SARS Coronavirus Nucleocapsid Protein-Based ELISA is more Specific for Serodiagnosis of SARS

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Severe acute respiratory syndrome (SARS) is a recently emerged human disease associated with pneumonia. The disease has affected 30 countries in 5 continents, with more than 8400 cases and more than 910 deaths. Since the recognition of the SARS coronavirus (SARS-CoV) as the agent causing SARS in April 2003, enormous international efforts to develop laboratory tests for SARS have occurred. Despite sensitive methods for detecting virus genetic material, detection of virus in the early stages of illness may still be difficult, and the final assessment of whether an individual has been infected may depend on detection of antibody to virus. To develop a safe and reliable diagnosis method for SARS, we cloned the whole range and the N-terminal 121 amino acids truncated SARS-CoV nucleocapsid protein (N protein and N₋₁₂₁ protein) gene into plasmid and expressed them in *E. coli*. Serum samples collected from 175 healthy volunteers in Vietnam before the SARS outbreak occurred were used to for the assessment of our newly developed indirect IgG ELISA using recombinant N protein and N₋₁₂₁ protein as assay antigens. While ELISA using N protein showed relatively high nonspecific reaction which was 38/175 (21.7%) and the titer ranging 1:100-1:3200, however N₋₁₂₁ protein could drastically reduce it up to 11/175 (6.3%) and the titer ranging 1:100-1:200. To assess the sensitivity of IgG ELISA using N₋₁₂₁ protein, serially collected serum samples from 37 SARS probable (including 15 cases confirmed with RT-PCR) cases were examined. Thirty six patients (97.3%) showed IgG seroconversion and the titer was ranging 1:600-1:204,800. The timing of IgG sero-conversion against N₋₁₂₁ protein after onset of illness were 22.2% in the first week, 69.4% in the second week and reached to 100% in the third week. Our data indicate that our newly developed SARS-CoV N₋₁₂₁ protein-based IgG ELISA is a safe, specific and sensitive test for diagnosing SARS-CoV infection. It could serve as a simple, sensitive, and specific test for clinical diagnosis and large-scale sero-epidemiological studies.

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