Journal of Infectious Diseases & Research
JIDR, 4(S1): 08
www.scitcentral.com
ISSN: 2688-6537
Abstract: Open Access

Large Scale Production and Characterization of SARS-CoV-2 Whole Antigen for Serological Test Development

Helena Cerutti*, Veronica Ricci, Giulia Tesi, Claudia Soldatini, Marinunzia Castria, Marco Natale Vaccaro, Stefania Tornesi, Simona Toppi, Silvana Verdiani and Alessandra Brogi

Diesse Diagnostica Senese SpA, Siena, Italy

Published May 19th, 2021

ABSTRACT

Background: The rapid spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has generated a pandemic with alarming rates of fatality worldwide. This situation has had a major impact on clinical laboratories that have attempted to answer the urgent need for diagnostic tools, since the identification of coronavirus disease 2019 (COVID-19). Development of a reliable serological diagnostic immunoassay, with high levels of sensitivity and specificity to detect SARS-CoV-2 antibodies with improved differential diagnosis from other circulating viruses, is mandatory.

Methods: An enzyme-linked immunosorbent assay (ELISA) using whole inactivated virus cultured in vitro, was developed to detect viral antigens. Western Blotting and ELISA investigations were carried out with sera of convalescent patients and pre-pandemic sera from healthy donors. Both analyses were concurrently performed with specific recombinant Monoclonal Antibodies to verify the findings.

Results: Preliminary data from 10 sera (5 patients with COVID-19, and 5 healthy controls) using this immunoassay are very promising, successfully identifying all of the confirmed SARS-CoV-2-positive individuals.

Conclusion: These ELISA tests, using the whole inactivated virus, appear to be a specific and reliable method for detecting COVID-19 antibodies (IgG, IgM and IgA). The ability to analyze in a single test all viral structural proteins has proven to be a useful tool to identify individuals which have contracted the infection and developed immunity.

Keywords: COVID-19, ELISA, Native antigen, Serological test, Viral culture

Corresponding author: Cerutti Helena, DIESSE Diagnostica Senese S.p.A., Via Fiorentina, 1- c/o Toscana Life Sciences, 53100 Siena, Italy Tel: +39 0577 231243 E-mail: helenacerutti@diesse.it

Citation: Cerutti H, Ricci V, Tesi G, Soldatini C, Castria M et al. (2021) Large Scale Production and Characterization of SARS-CoV-2 Whole Antigen for Serological Test Development. J Infect Dis Res, 4(S1): 08.