Validation of SARS-CoV-2 Serological Essay, Bahrain Experience

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Background: The standard test for diagnosing Coronavirus disease (COVID-19) is the polymerase chain reaction (PCR) test. Since the start of the pandemic, there has been a rush in the development of tests that can detect the presence of antibodies produced by COVID-19 cases as a response to the exposure to the SARS-CoV-2 virus.

Objective: To evaluate the validity of the serology tests for detecting SARS-CoV-2 protective IgG antibodies.

Design: Cross-Sectional Prospective Study.

Setting: COVID-19 Testing and Caring Facilities, Kingdom of Bahrain.

Method: From 22 June to 1 July 2020, healthcare workers, non-national laborers, symptomatic and asymptomatic patients were included in the study. All patients underwent PCR and serology tests. The presence of IgG antibodies among participants were measured. The sensitivity and specificity of the serology tests were evaluated.

Result: Three hundred eighty-eight participants were included in the study, the mean age was 40±13 years. Two-hundred thirty-two (59.7%) were males and 242 (62.3%) were Bahrainis. Seventy-three (18.8%) were healthcare workers, 87 (22.4%) were non-national laborers, 109 (28.1%) were symptomatic and 119 (30.7%) were asymptomatic. One hundred sixty-four (42.2%) participants were COVID-19 positive. Ninety-six (24.7%) had a positive serology test with IgG level >1.4. The sensitivity of the serology test at <7 days was 28% (CI: 19.4%-38.4%), at 7-13 days was 77.8% (CI: 60.9%-89.9%) and >14 days was 84.4% (CI: 67.2%-94.7%). The specificity of the test was 93.3% (CI: 89.2%-96.2%).

Conclusion: The sensitivity of the serology test to detect the IgG antibodies 14 days after testing positive with COVID-19 was 84% and the specificity was 93.3%. The result supports the use of the test in a serosurvey study.

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