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Editorial

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Briefing of Serological Laboratory Assay Tests for Covid 19

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While RT-PCR-based viral RNA detection has been widely used in diagnosis of COVID-19, it cannot be used to monitor the progress of the disease stages and cannot be applied to broad identification of past infection and immunity. Serological testing is defined as an analysis of blood serum or plasma and has been operationally expanded to include testing of saliva, sputum, and other biological fluids for the presence of immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies. This test plays an important role in epidemiology and vaccine development, providing an assessment of both short-term (days to weeks) and long-term (years or permanence) trajectories of antibody response, as well as antibody abundance and diversity. IgM first becomes detectable in serum after a few days and lasts a couple of weeks upon infection and is followed by a switch to IgG. Thus, IgM can be an indicator of early stage infection, and IgG can be an indicator of current or prior infection. IgG may also be used to suggest the presence of post-infection immunity. In recent years, the sophistication and sensitivity of immunological assays have increased not only for the detection of antibodies themselves but also for the application of antibodies (primarily monoclonal antibodies) to the detection of pathogen derived antigens.

These tests have a huge potential for the epidemiology of COVID-19, [1,2–5] but test results can be impacted by at least three situations: (1) a subset of subjects with a positive result from molecular genetic assays for SARS-CoV-2 infection are seronegative due to the lag in antibody production following infection, (2) the subjects may be seropositive yet negative for molecular genetic assay results reflecting clearance of an earlier, milder infection, and (3) limitation in sensitivity and specificity of the assays. The last issue is particularly important because even a small percentage of false positive results due to low specificity (cross reaction) may lead to misleading predictive antibody prevalence among a given population, which may have undesirable impact on the socioeconomic decisions and overall public confidence in the results.[6,7] The determination of SARS-CoV-2 exposure relies largely on the detection of either IgM or IgG antibodies that are specific for various viral antigens including, but not exclusively, the spike glycoprotein (S1 and S2 subunits, receptor-binding domain) and nucleocapsid protein.

So, in short both molecular assays for detection of viral nucleic acid as well as serological and immunological assay test have different purposes and no one can replaced the other one. The molecular assays for detection for nucleic acid assays are useful in diagnostic purpose and among them RT- PCR is considered as gold standard test for diagnosis. While serological and immunological tests are useful for epidemiological and prognostic purpose.