THE AGA KHAN UNIVERSITY HOSPITAL CLINICAL LABORATORIES

UPDATE
Quantitative detection of SARS-COV-2 IgG antibody

Introduction:

SARS-CoV-2 is the causative agent of coronavirus disease 2019 (COVID-19) in humans. Given the acute and rapid onset of COVID-19, molecular testing of respiratory tract sample(s) to detect SARS-CoV-2 RNA remains the preferred diagnostic test for symptomatic patients. With disease progression the viral shedding decreases as the circulating antibody titers rise to detectable level. Thus, there is increasing interest for use of serologic assays to detect IgG antibody against SARS-CoV-2. Unlike molecular testing, *detection of an immune response to the virus is an indirect marker of infection.* Antibody tests may aid diagnosis and management of COVID-19 and provide insights into the kinetics of the immune response. AKU clinical Microbiology section is pleased to inform the availability of new quantitative COVID-19 antibody test. This test primarily detects IgG antibody against spike protein. The IgG antibodies against both S1 and S2 components of spike proteins is detected.

Intended Use:
1.   Clinical Diagnosis and Screening for infection:
The SARS-CoV2 IgG assay is intended to aid in diagnosis of COVID-19 infection. Reports from China suggest *combining PCR and serological* testing significantly increased the sensitivity of COVID- 19 diagnosis. Antibody based test is particularly valuable in patients presenting in late phase of disease (day 7 onwards) and exhibit 90% sensitivity after day 12 post-onset. The Liason SARS-CoV-2 S1/S2 IgG test should not be used as the sole basis to diagnose or exclude SARS-CoV2 infection or to inform about infection status.

2.   SARS-CoV-2 Seroprevalence Studies:
SARS-CoV 2 IgG antibody test is also valuable in assessing the disease prevalence in the community for seroprevalence studies at local and national level, for epidemiology and government-based surveillance agencies. Serologic testing to detect IgG-class antibodies against SARS-CoV-2 will play an essential role in determining the true prevalence of this virus in the community.

3.   Immune status following vaccination:
SARS-CoV-2 serologic testing for the presence of anti-SARS-CoV-2 IgG antibodies will also be useful to determine the immune status of an individual following vaccination.

Principle:
Chemiluminiscence immunoassay to detect anti-SARS-CoV-2 IgG antibody

Specimen collection, storage and transport:
3-5 mL blood in gel tube or 1 ml serum is required for testing. Specimens should be stored and transported to lab at room temperature.

Rejection criteria:
Haemolysed, lipemic and icteric specimens should not be accepted because free hemoglobin, high levels of lipids and bilirubin may interfere with the test.

Schedule:

The assay will be performed daily (Monday to Sunday) and reported same day by 7:00 p.m. (cut-off time: 11 a.m.).

References:

1.   Theel et al. The Role of Antibody Testing for SARS-CoV-2: Is There One? J Clin Micro Apr 2020, JCM.00797-20; DOI: 10.1128/JCM.00797-20

PLEASE FILE FOR QUICK REFERENCE

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