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LETTER TO EDITOR

Performance of selected SARS-CoV-2 antibodies immunoassays

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Dear Editor,

The world has been shocked with the emergence of a novel virus known as SARS-CoV-2, a new member of the coronaviruses causing a pandemic globally. Real-time reverse-transcriptase PCR (RT-PCR) has remained as the mainstay of testing for early detection of the virus among exposed and suspected patients.[1] Many have raised questions on the roles of antibody testing in detecting patients with the disease. As clearly stated, serology test cannot be used as a standalone test to diagnose acute SARS-CoV-2 infections and manage the infected patient clinically. With a continuous clinical suspicion of COVID-19 and the second nucleic acid testing is still negative, two-point serum collection for antibody detection with (semi)quantitative serological assay in acute phase and 2-4 weeks later can be collected.[2]

The most sensitive and earliest serological marker is total antibodies, levels of which begin to increase from the second week of symptom onset.[3] Although IgM and IgG ELISA have been found to be positive even as early as the fourth day after symptom onset, higher levels occur in the second and third week of illness.[4] The presence of antibodies was <40% among patients within 1-week since onset, and rapidly increased to 94.3% (IgM) and 79.8% (IgG) since day-15 after onset.[5]

Institute for Medical Research (IMR) is one of the reference laboratories responsible for the COVID-19 test kits evaluation including the antibody tests for COVID-19. All kits are evaluated against well-characterised (IgM and IgG status of each selected samples were known) panels for the SARS-CoV-2 antibodies. Sera were collected from patients as part of routine diagnostic tests and management of COVID-19. The sera were re-identified and anonymized. The preparation of panels was based on the available kits in our laboratory at that particular point of time which had determined the characteristics of each serum received. Sera were collected from COVID-19 infected patients on day 5-8 day or on discharge.[6] Each kit was tested for 50 positive and 50 negative samples, respectively. Both Elecsys Anti SARS-CoV-2 and SARS-Cov-2 IgG were evaluated using the same panel. The kits that have been evaluated are depicted in the Table 1 below.

Table 1: Comparison on the performance of the kits evaluated

Test Name	Elecsys Anti SARS-CoV-2	SARS-CoV-2 IgG	Total Antibody COV2T assay
Test principle	Electrochemiluminescence immunoassay "ECLIA", uses a recombinant protein representing the nucleocapsid (N) antigen for the determination of antibodies against SARSCoV2.	Chemiluminescent microparticle immunoassay (CMIA) used to detect IgG antibodies to the nucleocapsid (N) protein of SARS-CoV-2	Acridinium ester chemiluminescence assay to detect antibodies to the spike protein (S) of SARS-CoV-2
Intended use	Qualitative detection of antibodies to SARSCoV2	Qualitative detection of IgG antibodies to SARS-CoV-2	Qualitative detection of antibodies to SARSCoV2
Sample	Serum, plasma	Serum, plasma	Serum, plasma
Equipment	Cobas e 411 analyser	ARCHITECT i System	ADVIA Centaur
Results	Sensitivity 100% Specificity 100%	Sensitivity 98% Specificity 100%	Sensitivity 94% Specificity 100% (Results were shared and the kit was evaluated by National Public Health Laboratory, Sg. Buloh)

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The performance results showed these commercial kits have good sensitivity and specificity results. Although each kit has a different purpose in diagnosing antibodies against COVID-19, each of the kit has a value to add on in assisting to diagnose COVID-19 in a patient.

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REFERENCES

1. Guidelines COVID-19 Management In Malaysia No. 5/2020 (http://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm)
2. Diagnostic testing for SARS-CoV-2: Interim guidance. World Health Organization 2020; Available from: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications)
3. Lou B, Li T-D, Zheng S-F, et al. Serology characteristics of SARS-CoV-2 infection after exposure and post-symptom onset. Eur Respir J 2020; 56: 2000763 [https://doi.org/10.1183/ 13993003.00763-2020].
4. Wölfel R, Corman VM, Guggemos W, et al. Virological assessment of hospitalized patients with COVID-2019. Nature. 2020. Published online April 1, 2020.
5. Zhao J, Yuan, Q, Wang H, et al. Antibody Responses to SARS-CoV-2 in Patients With Novel Coronavirus Disease 2019, Clin Infect Dis 2020 Nov 19;71(16):2027-2034.
6. Annex 5c. Flow Chart for Laboratory Diagnosis of SARS-CoV-2 in Suspected Case of COVID-19 Admitted to the Hospital, COVID-19 Management Guidelines in Malaysia No.5 / 2020 (Latest Update on 05 OGOS 2021) (https://covid-19.moh.gov.my/garis-panduan/garis-panduan-kkm/Annex_5c_edited_11112020.pdf)