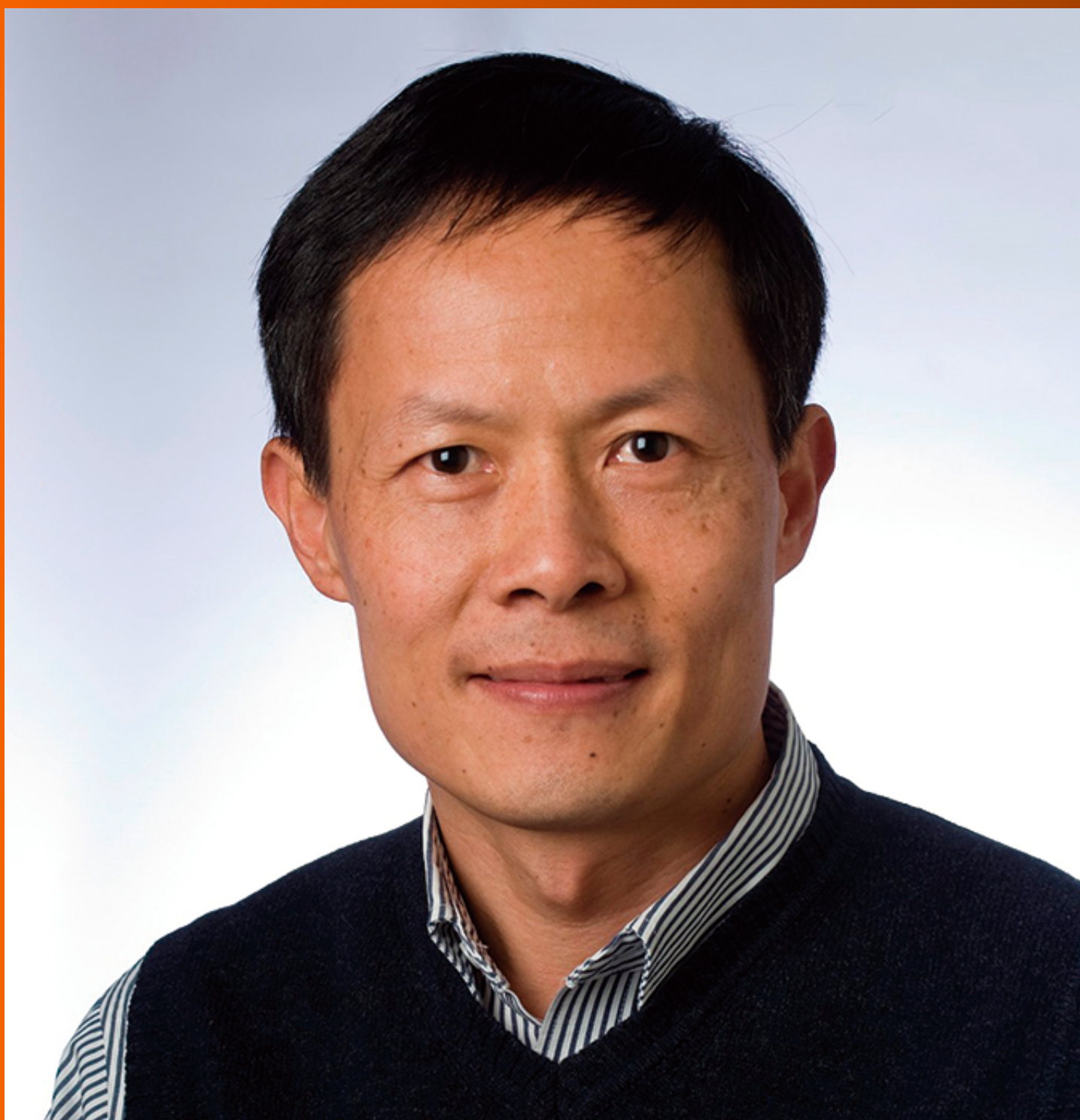


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Performance of a serological IgM and IgG qualitative test for COVID-19 diagnosis: An experimental study in Brazil

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Abstract

Qualitative antibody tests are an easy, point-of-care diagnostic method that is useful in diagnosing coronavirus disease 2019, especially in situations where reverse transcription-polymerase chain reaction is negative. However, some factors are able to affect its sensitivity and accuracy, which may contribute to these tests not being used as a first-line diagnostic tool.

Key Words: Serological test; IgM; IgG; COVID-19; Diagnosis; Antibody

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Core Tip: In this study we compared a quantitative enzyme-linked immunosorbent assay test that detects antibodies against the severe acute respiratory syndrome coronavirus 2 S1 epitope with the qualitative test. Our results demonstrate that the quantitative tests have significantly higher sensitivity rates, evidencing limitations in the use of the qualitative antibody detection test as a first-line diagnostic tool.

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TO THE EDITOR

We read with interest a retrospective study that assessed whether serological rapid antibody tests would be effective in the diagnosis of coronavirus disease 2019 (COVID-19) pneumonia in patients whose reverse transcription-polymerase chain reaction (RT-PCR) tests were negative, despite having radiological and clinical features consistent with this condition[1]. The authors evaluated and reported the clinical aspects, laboratory results, and radiological findings of 80 suspected COVID-19 patients who had at least two negative consecutive RT-PCR tests and underwent rapid serological antibody testing. In this sense, Colloidal Gold severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) IgG/IgM Rapid Test (Beijing Hotgen Biotech Co., Ltd) was used, which is a lateral flow chromatographic immunoassay detecting total antibodies produced against the SARS-CoV-2. Therefore, the specific serological total IgM/IgG antibodies against SARS-CoV-2 were detected in 22 of these patients. The authors, then, concluded that rapid serological antibody tests may be a suitable alternative in the diagnosis of suspected COVID-19 cases, especially in highly suspected cases with negative RT-PCR results.

Regarding COVID-19 diagnosis, nucleic acid amplification tests are considered as the most sensitive ones, with RT-PCR being the gold standard method, with an overall sensitivity of 0.96 (95% confidence interval [CI]: 0.93-0.98) and false negative rate of 0.06 (95% CI: 0.04-0.08), according to a recent meta-analysis[2]. On the other hand, chest CT scan is another fundamental piece for the diagnosis of COVID-19 and monitoring of the evolution of the patient's condition[3]. Although the identification of typical lesions caused by SARS-CoV-2 is relevant, presenting a high sensitivity, it has a low specificity, since imaging findings may also be present in other viral infections with similar ongoing symptoms to COVID-19[4].

In this sense, serological tests emerged in the SARS-CoV-2 pandemic to diagnose the infection after 14 d, since this is the cut-off period for reliable detection of amplification methods[5]. One study analyzed samples of SARS-CoV-2-positive patients by RT-PCR test, SARS-CoV-2 RT-PCR-negative patients with a clinical picture of COVID-19, and controls. General sensitivity for IgG was around 80.0% for the chemiluminescence enzyme immunoassays (CLIA), enzyme-linked immunosorbent assays (ELISA), and lateral flow immunoassays (LFIA) and the sensitivity of IgG reached 100.0% when the blood was obtained 15 d after the symptoms appeared. Overall, IgG specificity was $\geq 95.8\%$. In addition, the same study identified an IgM sensitivity of 81.8% and specificity of 95.3% in LFIA, which were 100% after 15 d of symptom onset[6]. Otherwise, in a meta-analysis study, the authors verified the pooled sensitivity and specificity of IgG and IgM of the above cited tests and observed wide 95% CIs, varying from 46.2% to 100% (CLIA), 75.6% to 90.9% (ELISA), and 49.3% to 79.3% (LFIA), which led the authors to emphasize that the data do not support the continued use of existing point-of-care serological tests and that further studies are needed to assess the accuracy of serological tests[7].

Another meta-analysis study by analyzing RT-PCR, immunological tests, and computed tomography (CT) demonstrated that the combination of IgM and IgG antibodies yielded a sensitivity of 84.5% and specificity of 91.6%, the RT-PCR test in sputum samples and CT obtained a sensitivity of 97.2% and 91.9%, respectively, but CT had a low specificity (25.1%). The authors corroborated the consensus of the RT-PCR method being the gold standard, but recommended the combination of different tests to improve the sensitivity and specificity of the diagnosis[8].

In respect to our study, the experience with EDI™ Novel Coronavirus COVID-19 ELISA Kit Flyer IgM and IgG (Epitope diagnosis Inc São Diego, EUA) qualitative test differs from the conclusion of Yıldırım *et al*[1]. Our team compared a quantitative ELISA test that detects antibodies against the SARS-CoV-2 S1 epitope with the EDI™ Novel Coronavirus COVID-19 ELISA Kit Flyer IgM and IgG (Epitope Diagnosis Inc San Diego, USA), which is a qualitative test, that is, it indicates the presence or absence of the virus without quantifying the viral load[9]. Eighty Brazilian patients were included in this study (47 adults, mean age of 41.5 ± 12.2 , and 33 children, mean age of 9.7 ± 2.9), and among them, 21 were RT-

PCR positive for COVID-19 and 59 were negative.

Overall, our results demonstrated that the sensitivity, specificity, accuracy, positive predictive values and negative predictive values of IgM detection were 19.05%, 100.0%, 78.7%, 100.0% and 77.6%, respectively, whereas the corresponding values of IgG were 38.1%, 100.0%, 83.7%, 100.0% and 81.9%, respectively. Notably, four children included in our study had severe multisystem inflammatory syndrome (MIS-C), which in most cases is a post-acute manifestation of COVID-19. Among the four children with MIS-C, two were RT-PCR negative, IgM was not detected in the serum of these children, but IgG was positive in three of them. Therefore, more accurate tests are necessary, not only to improve the diagnosis of COVID-19, but also of MIS-C especially because the direct detection of SARS-CoV-2 is less frequent in this severe disease. It is worth mentioning that, as shown in other studies, when comparing a quantitative ELISA test with a qualitative test, the sensitivity was much higher in the first one, even without differences in the duration of time from the onset of the first symptoms and blood collection (data not shown).

To conclude, despite the putative benefit of qualitative antibody tests in diagnosing COVID-19 in patients in whom RT-PCR test was negative, the low sensibility of some testing kits limits their use as a first-line diagnostic tool. Thus, we suggest qualitative tests to be used as an adjunctive tool in specific situations, of note: (1) In patients whose clinical picture indicates COVID-19, yet RT-PCR is negative; and (2) In the identification of past infections, until advances in the field improve the performance of rapid tests or further studies clarify the divergent results regarding the sensibility and specificity of these diagnostic methods.

FOOTNOTES

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